



## Current Agreements

### Dealdoc

#### Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated)

GSK

Adolor

Apr 15 2002

## Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated)

<b>Companies:</b>	<a href="#">GSK</a> <a href="#">Adolor</a>
<b>Announcement date:</b>	Apr 15 2002
<b>Deal value, US\$m:</b>	270.0 : sum of upfront and milestone payments <a href="#">Third amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">Termination of licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">Distribution agreement for Entereg (alvimopan)</a> <a href="#">Second amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)</a> <a href="#">First amendment to distribution agreement for Entereg (alvimopan)</a>
<b>Related contracts:</b>	

- [Details](#)
- [Financials](#)
- [Termsheet](#)
- [Press Release](#)
- [Filing Data](#)
- [Contract](#)

### Details

<b>Announcement date:</b>	Apr 15 2002
<b>Start date:</b>	Apr 14 2002
<b>Termination date:</b>	Sep 02 2008
<b>Industry sectors:</b>	Bigpharma Pharmaceutical
<b>Therapy areas:</b>	Gastrointestinal » Symptoms » Bowel movement Hospital care » Surgery
<b>Technology types:</b>	Drug delivery Small molecules Co-development Co-market Co-promotion
<b>Deal components:</b>	Licensing Marketing Promotion Termination
<b>Stages of development:</b>	Phase III
<b>Geographic focus:</b>	Worldwide

### Financials

<b>Deal value, US\$m:</b>	270.0 : sum of upfront and milestone payments
<b>Upfront, US\$m:</b>	50.0 : upfront payments
<b>Milestones, US\$m:</b>	220.0 : clinical and regulatory payments

## Termsheet

15 April 2002

Adolor and GlaxoSmithKline announced today a collaboration agreement for the exclusive worldwide development and commercialization of alvimopan (formerly known as ADL 8-2698).

Alvimopan is an orally administered treatment that is in Phase 3 clinical development for the management of bowel paralysis after surgery (postoperative ileus, POI) and constipation caused by opioid use.

In addition, the companies have agreed to co-develop alvimopan for a number of other indications, both acute and chronic, which would involve the use of alvimopan in out-patient settings.

GlaxoSmithKline will pay Adolor a signing fee of \$50 million and clinical and regulatory milestone payments of up to \$220 million over the term of the agreement depending on the progress of the various indications.

In the U.S., Adolor and GlaxoSmithKline will co-develop and co-promote alvimopan and share development expenses and commercial returns.

Adolor will lead the development, marketing, and co-promotion strategy for acute-care indications, which will be targeted to hospitals and surgeons.

GlaxoSmithKline will lead the development, marketing, and co-promotion for chronic-care indications targeted to community-based physicians.

## Press Release

14 June 2011

Adolor Corporation Announces Agreement to Acquire Full Ownership of ENTEREG (alvimopan)

EXTON, Pa.--(BUSINESS WIRE)--Adolor Corporation (NasdaqGM: ADLR) today announced that it has entered into an agreement with GlaxoSmithKline (GSK) whereby Adolor will reacquire all rights to Adolor's FDA-approved product ENTEREG® (alvimopan). The transaction is expected to close in September 2011. Currently, ENTEREG is co-promoted by Adolor and GSK in the United States.

"We are thrilled to have an agreement to acquire the rights to ENTEREG held by GSK," said Michael R. Dougherty, President and Chief Executive Officer. "We see continuing revenue growth ahead for ENTEREG, building upon the solid foundation laid by GSK and Adolor over the past several years. We expect ENTEREG to generate meaningful cash flows for Adolor over the next year and into the future."

Dougherty continued, "With full ownership of a key hospital product in ENTEREG and data just ahead from our Phase 2 program with ADL5945 for the treatment of opioid-induced constipation, we believe Adolor is well positioned to create compelling strategic value for our stockholders."

Under the agreement, Adolor has agreed to pay to GSK \$25 million cash, staged over a six-year period, with \$2.5 million payable in 2011, tiered, mid-single digit royalties on annual net sales and a further one-time, sales-related milestone of \$15 million.

"Since 2008, nearly 30 Adolor employees have been focused on the marketing and selling of ENTEREG to hospitals and physicians," said Michael D. Adelman, Vice President, Marketing and Sales. "We have extensive knowledge of this marketplace, and are excited about the prospect of now controlling all aspects of the promotional effort. Over the next several months, we intend to approximately double the size of our ENTEREG team, and anticipate a smooth transition working with GSK."

### Conference Call Information

Adolor's management will host a conference call with investors to discuss this transaction on Wednesday, June 15, 2011, beginning at 8:30 a.m. ET.

To participate in the audio portion and have the opportunity to pose questions, dial 800-688-0836 for domestic callers or 617-614-4072 for international callers, and enter Conference ID # 79902094. Investors also can listen to the call live by logging on to the Company's website at [www.adolor.com](http://www.adolor.com) and clicking on "Investor Insights," then "Calendar of Events."

A replay of the call will be available beginning approximately two hours after the event. To listen to a replay of the conference call, dial 888-286-8010 (domestic) or 617-801-6888 (international) and enter Conference ID # 80030752 or listen via Adolor's website. The replay will be available for one week.

### About ENTEREG

Adolor markets and sells ENTEREG in the United States. ENTEREG is indicated to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. ENTEREG is available only for short-term (15 doses)

use in hospitalized patients. Only hospitals that have registered in and met all of the requirements for the ENTEREG Access Support and Education (E.A.S.E.) program may use ENTEREG. For more information on ENTEREG, including its full prescribing information, the Boxed Warning regarding short-term hospital use and the E.A.S.E.® Program, visit [www.ENEREG.com](http://www.ENEREG.com).

#### About Adolor

Adolor Corporation is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain and pain management products. The Company's research and development pipeline includes: ADL5945 and ADL7445, novel mu opioid receptor antagonists undergoing clinical development for chronic OIC; and several earlier-stage compounds under development for the management of pain and CNS disorders.

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2 September 2008

#### Adolor Regains Rights to Entereg(R) (alvimopan) for OBD

EXTON, Pa.--(BUSINESS WIRE)--Sept. 2, 2008--Adolor Corporation (Nasdaq: ADLR) announced today that GlaxoSmithKline (GSK) has returned to Adolor worldwide rights related to Entereg(R) (alvimopan) for chronic opioid bowel dysfunction (OBD). GSK is retaining rights to Entereg for postoperative ileus (POI), and the companies will continue to collaborate on the development and commercialization of Entereg for POI in the United States.

Adolor announced in July 2008 that the U. S. Food and Drug Administration (FDA) lifted the clinical hold on the OBD Investigational New Drug Application.

"There is a large, unmet need for treatment options for the many patients who suffer with chronic OBD," said Michael R. Dougherty, president and chief executive officer of Adolor. "Adolor maintains a portfolio of development candidates that may potentially serve this patient population, including Entereg, our Combination Product Program, and additional earlier stage compounds. We intend now to explore discussions with potential partners regarding this portfolio, and to submit to the FDA for review a protocol for an additional study of Entereg in OBD under a Special Protocol Assessment."

Mr. Dougherty continued, "We value our relationship with GSK for Entereg in POI a great deal and are pleased with the early progress of our efforts under the E.A.S.E.(TM) Program. We will continue to work closely with GSK in implementing this Program, and in making this important new product available to bowel resection patients and surgical teams."

GSK also returned to Adolor rights related to Entereg for irritable bowel syndrome (IBS) and non-opioid induced forms of constipation or bowel dysfunction. There have been no active development programs for these indications.

#### About Adolor Corporation

Adolor Corporation (Nasdaq: ADLR) is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain management products. By applying its knowledge and expertise in pain management, along with ingenuity, Adolor is seeking to make a positive difference for patients, caregivers and the medical community. For more information, visit [www.adolor.com](http://www.adolor.com).

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20 May 2008

#### Adolor and GlaxoSmithKline Announce FDA Approval of Entereg(R) (alvimopan) for the Management of Postoperative Ileus (POI)

##### -First FDA Approved Therapy for POI-

EXTON, Pa. & PHILADELPHIA--(BUSINESS WIRE)--May 20, 2008--Adolor Corporation (Nasdaq:ADLR) and GlaxoSmithKline (NYSE:GSK) announced today that the U.S. Food and Drug Administration has approved Entereg(R) (alvimopan) capsules to help patients regain gastrointestinal (GI) function earlier following bowel resection surgery. Postoperative ileus (POI) is a condition that affects almost all patients undergoing this type of surgery and can cause significant discomfort in addition to prolonging hospital stays for patients. Entereg is indicated to accelerate upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Entereg will be available for short-term use in hospitals registered under the Entereg Access Support and Education (E.A.S.E.(TM)) program.

"The approval of Entereg in POI represents a major milestone for Adolor, and is the culmination of a substantial collaborative effort among Adolor, GlaxoSmithKline, and our clinical investigators," said Michael R. Dougherty, president and chief executive officer of Adolor Corporation. "Entereg is the first and only product that has demonstrated the ability to address this serious condition, which has negative consequences for patients, and imposes considerable expense on the healthcare system."

"We are proud to join Adolor in offering bowel resection patients and surgical teams the only therapy proven to consistently accelerate GI recovery in patients and time to hospital discharge order written," said Anne Whitaker, vice president of GlaxoSmithKline's recently formed Critical and Supportive Care Business Unit. "Entereg is an important new product for GSK to offer our longstanding hospital customers."

Entereg is a peripherally acting mu-opioid receptor (PAM-OR) antagonist. The benefits of Entereg were demonstrated in five clinical studies in which all of the more than 2,500 bowel resection patients enrolled (including those in the placebo group) were placed on an accelerated postoperative care pathway, which included nasogastric tube removal before the first postoperative dose, early ambulation and early feeding. The endpoint of these studies was time to achieve recovery of both upper and lower GI function, reported as GI2 data in the package insert, representing resolution of POI. Entereg accelerated the time to recovery of GI function and reduced the time to hospital discharge order written as compared to placebo. Entereg did not reverse opioid analgesia in these patients.

"Delayed recovery of GI function, often called postoperative ileus, is one of the principal causes of patient discomfort and extended hospital stay following bowel resection surgery," said Dr. Anthony Senagore, vice president research, Spectrum Health and Professor of Surgery, Michigan State University in Grand Rapids. "Entereg is a welcome and much needed addition to peri-operative care because it allows us to manage POI without compromising analgesia. With this medication, we have an opportunity to help bowel resection patients recover their GI function more quickly and get them discharged earlier. Since many of these patients are undergoing resections for colorectal cancer or other serious conditions, earlier return to normal feeding and GI function is a positive result for these patients."

POI is thought to be caused in part by the interaction of opioid pain relievers with mu-opioid receptors in the GI tract inhibiting bowel function and motility. It is associated with abdominal distension and bloating, persistent abdominal pain, nausea and vomiting, variable reduction of bowel sounds, delayed passage of or an inability to pass flatus (gas) or stool, and an inability to tolerate oral intake or progress to a solid diet.

Opioid analgesics, such as morphine, are widely used for the treatment of postoperative pain. Entereg works by binding to mu-opioid receptors in the gut, thereby selectively inhibiting the negative effects of opioid medications on GI function and motility.

Entereg is for hospital use only. The recommended adult dose of Entereg is a single 12 mg capsule administered orally 30 minutes to five hours prior to surgery followed by a 12 mg capsule twice daily beginning the day after surgery for a maximum of seven days or until discharge, not to exceed 15 doses (see Important Safety Information below).

The FDA lifted the clinical hold on the Entereg capsule investigational new drug application (IND) for POI. The companies plan to commence a study in patients undergoing radical cystectomy, another population in which POI is a significant burden, as part of a postmarketing commitment.

#### E.A.S.E.(TM) Program for Hospital Registration

The FDA has approved Entereg with a Risk Evaluation and Mitigation Strategy (REMS). As part of the REMS, Adolor has developed the Entereg Access Support and Education (E.A.S.E.) program. Under the E.A.S.E. program, Entereg will be made available only to hospitals that complete a registration process. The E.A.S.E. program is designed to maintain the benefits associated with short-term use in the bowel resection population and prevent long-term, outpatient use.

#### Important Safety Information About Entereg

The Entereg full prescribing information has a boxed warning that states Entereg is available only for short-term (15 doses) use in hospitalized patients. Only hospitals that have registered in and met all requirements of the Entereg Access Support & Education (E.A.S.E.) program may use Entereg.

Entereg is contraindicated in patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking Entereg.

There were more reports of myocardial infarctions in patients treated with alvimopan 0.5 mg twice daily compared with placebo-treated patients in a 12-month study of patients being treated with opioids for chronic pain. This imbalance has not been observed in studies in patients undergoing bowel resection surgery who have received alvimopan 12 mg twice daily for up to 7 days. A causal relationship with alvimopan has not been established.

Overall, the incidence of adverse events in short-term surgical clinical trials was similar between patients receiving either Entereg or placebo. In clinical studies, the most common adverse reactions in patients receiving Entereg following bowel resection were anemia, dyspepsia, hypokalemia, back pain, and urinary retention.

For more information about Entereg, including full prescribing information, visit [www.entereg.com](http://www.entereg.com).

#### About Adolor Corporation

Adolor Corporation (Nasdaq:ADLR) is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain management products. By applying its knowledge and expertise in pain management, along with ingenuity, Adolor is seeking to make a positive difference for patients, caregivers and the medical community. For more information, visit [www.adolor.com](http://www.adolor.com).

#### About GlaxoSmithKline

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit GlaxoSmithKline on the World Wide

15 April 2002

#### Adolor and GlaxoSmithKline Announce Worldwide Development and Commercialization Agreement for Alvimopan

EXTON, Pa., and LONDON, Apr 15, 2002 -- Adolor Corporation (Nasdaq: ADLR) and GlaxoSmithKline (NYSE: GSK) announced today a collaboration agreement for the exclusive worldwide development and commercialization of alvimopan (formerly known as ADL 8-2698). Alvimopan is an orally administered treatment that is in Phase 3 clinical development for the management of bowel paralysis after surgery (postoperative ileus, POI) and constipation caused by opioid use. In addition, the companies have agreed to co-develop alvimopan for a number of other indications, both acute and chronic, which would involve the use of alvimopan in out-patient settings.

Under the terms of the agreement, GlaxoSmithKline will pay Adolor a signing fee of \$50 million and clinical and regulatory milestone payments of up to \$220 million over the term of the agreement depending on the progress of the various indications.

In the U.S., Adolor and GlaxoSmithKline will co-develop and co-promote alvimopan and share development expenses and commercial returns. Adolor will lead the development, marketing, and co-promotion strategy for acute-care indications, which will be targeted to hospitals and surgeons. GlaxoSmithKline will lead the development, marketing, and co-promotion for chronic-care indications targeted to community-based physicians.

Alvimopan is a mu opioid antagonist which, when given orally, is being clinically evaluated for its ability to improve bowel motility in postoperative patients while not reversing the centrally-mediated analgesic effects of the opioid. As a result, it is anticipated that the bowel may recover faster and patients could be discharged from hospital earlier. The potential for patients to suffer less pain and discomfort and less nausea and vomiting with alvimopan was highlighted in a Phase II POI study published as a leading article in the September 27, 2001 edition of The New England Journal of Medicine and in an editorial in the same edition. The potential benefits to patients and healthcare providers are significant.

"GlaxoSmithKline, with its extensive marketing and sales infrastructure, was our partner of choice for maximizing the commercial potential of alvimopan," commented John Farrar, Ph.D., President and Chief Executive Officer of Adolor Corporation. "In addition, a crucial element of the transaction for us was the opportunity to co-promote in the U.S. and thereby fully share in the future value of the product. Finally, this collaboration positions Adolor for strong future growth by providing the funds to develop our pipeline and in-license additional products."

"We look forward to working with Adolor in pursuing a much-needed improvement in reversing the adverse effects of opioids, said Dr. Tachi Yamada, Chairman R&D, GlaxoSmithKline. "Our objectives are to help patients recover from surgery faster and get out of the hospital sooner, and also to improve the quality of life for those on chronic opioid medication. GSK has a wealth of development and commercialization expertise in gastrointestinal diseases and in that regard we bring real value to Adolor as a partner."

Adolor may elect at a later date to participate in Phase 3 development, co-promote and receive a share of the U.S. profits for chronic indications other than constipation caused by opioid use, or alternatively, receive royalties on net sales. Adolor will also have the right to co-promote a GlaxoSmithKline hospital product for sale in the U.S. only.

#### Background Notes to Editor:

POI All patients undergoing major abdominal surgery experience bowel paralysis of variable duration. This phenomenon, known as postoperative ileus or POI, is exacerbated and prolonged by the use of opioids for pain relief. Such patients suffer nausea and vomiting, cannot eat or drink, have more postoperative pain and stay in hospital longer. There has been little advance in the treatment of POI since the 1930's, with nasogastric suction and intravenous fluids being the mainstay of management. Such interventions are uncomfortable for patients and resource intensive for surgical ward staff.

#### Major Abdominal Surgery

Major abdominal surgery includes procedures such as laparotomy, hysterectomy, colectomy and reversal of colostomy. It is estimated that several million major abdominal procedures are undertaken in the U.S. alone each year. Such procedures result in hospitalization lasting 3 to 15 days.

#### GI side effects of opioids

Morphine and other opioids are potent analgesics that work by stimulating mu-opioid receptors in the brain. However these receptors are also located in the wall of the gut and stimulation of the gut receptors results in the common unwanted effects of prolonged ileus in postoperative patients and constipation in patients who use oral opioids for severe chronic pain. Opioids can also cause nausea and vomiting in acute and chronic use.

#### How alvimopan works

Alvimopan is an orally administered mu opioid antagonist which is intended to reverse the effects of opioids in the gut in postoperative patients and chronic pain patients without affecting the centrally-mediated analgesic properties of the opioid. As a result, in postoperative patients, the

bowel may recover faster and patients may be discharged from hospital earlier. Research has suggested that many patients with severe pain on chronic opioids do not take adequate doses of their pain medication because of the severe constipation it causes, despite the use of various laxatives. Alvimopan, with its highly specific action in reversing opioid side effects on the gut, may offer the prospect of better tolerability and improved compliance in such patients.

#### Clinical Update

Adolor is currently conducting three pivotal Phase 3 trials evaluating alvimopan for the management of postoperative ileus, and one pivotal Phase 3 trial evaluating alvimopan in the treatment of opioid bowel dysfunction. The companies are targeting submission of the New Drug Application with the FDA for the management of postoperative ileus at the first half of 2003.

#### About Adolor Corporation

Adolor Corporation discovers, develops and plans to commercialize proprietary pharmaceutical products for the treatment of pain and to mitigate the side effects that are caused by current pain treatments. Adolor has a portfolio of product candidates in development in Phase 1 through Phase 3 clinical trials. These product candidates include our peripheral opioid analgesics and alvimopan, formerly known as ADL 8-2698, which is intended for the management of opioid bowel dysfunction and postoperative ileus. Adolor's product candidates target peripheral opioid receptors and are not expected to exhibit the dose-limiting side effects of existing opioid narcotics.

#### About GlaxoSmithKline

GlaxoSmithKline -- one of the world's leading research-based pharmaceutical and healthcare companies -- is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information, visit GlaxoSmithKline at <http://www.gsk.com>

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3 July 2008

#### Adolor Provides Update on Entereg(R) (alvimopan) OBD Program

##### FDA Lifts Clinical Hold on OBD IND

EXTON, Pa.--(BUSINESS WIRE)--July 3, 2008--Adolor Corporation (Nasdaq: ADLR) today issued an update on the Entereg(R) (alvimopan) Program for chronic opioid bowel dysfunction (OBD), under development in collaboration with GlaxoSmithKline (NYSE: GSK).

The U. S. Food and Drug Administration (FDA) has concluded that clinical investigations relating to alvimopan in OBD may now proceed, and has therefore lifted the clinical hold on the OBD Investigational New Drug Application.

"After a productive meeting and dialogue with FDA, we are very pleased to see the clinical hold lifted," said Michael R. Dougherty, president and chief executive officer of Adolor. "There remains a large, unmet need for treatment options for the many patients suffering from this debilitating condition."

Adolor understands that GSK is evaluating all options relating to the OBD Program, including whether to proceed with its involvement with the Program. The April 2002 Collaboration Agreement between Adolor and GSK provides that GSK may terminate the Agreement with respect to the OBD product, returning rights to the OBD product to Adolor, while retaining its rights to the postoperative ileus (POI) product.

Michael R. Dougherty said, "Should GSK determine to discontinue their involvement with the OBD Program, Adolor would expect to submit for review by FDA a protocol for an additional study in this indication."

GSK and Adolor are actively engaged in the commercialization of the recently approved Entereg for POI for bowel resection surgeries.

#### About Adolor Corporation

Adolor Corporation (Nasdaq: ADLR) is a biopharmaceutical company specializing in the discovery, development and commercialization of novel prescription pain management products. By applying its knowledge and expertise in pain management, along with ingenuity, Adolor is seeking to make a positive difference for patients, caregivers and the medical community. For more information, visit [www.adolor.com](http://www.adolor.com).

#### Filing Data

10K abstract - 2012

In April 2002, Adolor entered into a collaboration agreement with Glaxo Group Limited, or Glaxo, in which Glaxo received exclusive, worldwide rights to develop and commercialize ENTEREG for certain indications. In June 2011, Glaxo and Adolor entered into a termination agreement whereby Adolor agreed to reacquire Glaxo's rights to ENTEREG in exchange for Adolor's agreement to pay Glaxo: i) \$25.0 million, of which \$2.5 million was paid by Adolor prior to the acquisition, payable in annual installments through 2017; ii) tiered, single-digit royalties on annual net sales of ENTEREG, subject to reductions based upon certain conditions; and iii) a one-time, sales-based milestone of \$15.0 million upon achievement of a predetermined level of sales in a given year. Effective September 2011, Adolor assumed all responsibilities related to the

commercialization of ENTEREG pursuant to the termination agreement. The termination agreement expires on the date of the last commercial sale of the product by Adolor in the U.S. In December 2011, the Company assumed the obligations owed to Glaxo as a result of the acquisition of Adolor. The Company made a payment of \$3.0 million to Glaxo in September 2012, and the remaining \$19.5 million is payable in five installments over the next five years. The Company does not expect to achieve the one-time sales-based milestone in 2013. See Note F., "Fair Value Measurements," for additional information.

## Contract

### COLLABORATION AGREEMENT

dated as of April 14, 2002

by and between

ADOLOR CORPORATION

and

GLAXO GROUP LIMITED

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#### COLLABORATION AGREEMENT

This COLLABORATION AGREEMENT ("Agreement") dated as of April 14, 2002

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(the "Effective Date"), is made by and between ADOLOR CORPORATION, a Delaware

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corporation and having its principal office at 620 Pennsylvania Drive, Exton,

Pennsylvania 19341 ("Adolor"), and GLAXO GROUP LIMITED, a United Kingdom

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corporation, and having its principal office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("GSK"). Adolor and GSK

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may be referred to as a "Party" or together, the "Parties".

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## RECITALS

WHEREAS, Adolor is currently developing a compound known as alvimopan for postoperative bowel dysfunction and other gastrointestinal disorders;

WHEREAS, GSK has significant experience in the development, marketing and promotion of pharmaceutical products and believes it can make significant contributions to the successful development and commercialization of alvimopan;

WHEREAS, GSK and Adolor have complementary technology, capabilities and resources which are necessary for the development and commercialization of the Collaboration Products;

WHEREAS, GSK and Adolor are willing to undertake such development and commercialization activities and investment based on the coordination of such activities and investment provided by this Agreement similar to that of a single entity with respect to the Collaboration Products; and

WHEREAS, GSK and Adolor believe that a collaboration pursuant to this Agreement for the development, promotion and commercialization of alvimopan would be desirable and fully compatible with their respective business objectives and provide the most effective and efficient means to ensure that the Collaboration Products are developed and commercialized so as to maximize the return on investment for GSK and Adolor.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, Adolor and GSK, intending to be legally bound, hereby agree as follows:

## ARTICLE 1

### DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.1 "AAA" shall have the meaning set forth in Section 18.5.2.

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<PAGE>

1.2 "Additional Product" means a \*\* Product and any Product other

-----

than a POI Product, an OBD Acute Product, an OBD Chronic Product, a \*\* Product  
or an \*\* Product included by the Parties pursuant to Section 4.3.

1.3 "Adolor Housemark" means the name and logo of Adolor or an

-----

Affiliate of Adolor as identified by Adolor to GSK from time to time.

1.4 "Adolor Invention" means an Invention that is conceived or reduced

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to practice by an employee or agent of Adolor solely or jointly with a Third  
Party.

1.5 "Adolor Know-How" means all present and future Know-How that

-----

relates to the Collaboration Products, the Compound or the Adolor Inventions, to  
the extent necessary for GSK to perform its obligations or enjoy its rights  
under this Agreement, and which during the Term are in Adolor's or any of its  
Affiliates' possession or control and are or become owned by, or otherwise may  
be licensed by, Adolor. Adolor Know-How does not include any Adolor Patents.

1.6 "Adolor Patents" means all Patent Rights covering the

-----

Collaboration Products, the Compound or the Adolor Inventions which are or  
become owned by Adolor or Adolor's Affiliates, or as to which Adolor or Adolor's  
Affiliates are or become licensed, now or in the future, with the right to grant  
the sublicense rights granted to GSK under this Agreement, which Patent Rights  
cover the making, having made, use, offer for sale, sale or importation of  
Collaboration Products, and which existing Patent Rights are more specifically  
set forth on Schedule 1.6.

-----

1.7 "Adolor Product Marketing Contribution" means an amount equal to

-----

\*\* for Adolor Products in the applicable reporting period in the United States

less the following amounts: (a) \*\* of the Adolor Product constituting such \*\*;  
(b) the \*\*; (c) royalties paid to \*\* on account of sales of Adolor Products in  
\*\*, and (d) \*\*.

1.8 "Adolor Product Promotion Term" means the period of time beginning

-----

on the Effective Date and ending \*\* years after First Commercial Sale of a POI  
Product in the United States unless otherwise extended pursuant to the  
provisions of Section 16.2.

1.9 "Adolor Product Trademarks" shall have the meaning set forth in

-----

Section 2.4.1.

1.10 "Adolor Products" means a POI Product, an OBD Acute Product or any

-----

Additional Product designated by the Parties as an Adolor Product pursuant to  
Section 4.3.

1.11 "Adolor Reconciliation Report" shall have the meaning set forth in

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Section 6.7.5(a).

1.12 "Adolor Report" shall have the meaning set forth in Section 6.7.3.

-----

1.13 "Adverse Drug Experience" means any of: an "adverse drug

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experience," a "life-threatening adverse drug experience," a "serious adverse  
drug experience," or an "unexpected adverse drug experience," as those terms are  
defined at either 21 C.F.R.(S)312.32 or 21 C.F.R.(S)314.80.

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the Commission. Confidential treatment has been requested with respect to the  
omitted portions.

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1.14 "Affiliate" of a Party means any Person, whether de jure or de

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facto, which directly or indirectly controls, is controlled by, or is under  
common control with such Person for so long as such control exists, where



"control" means the decision-making authority as to such Person and, further, where such control shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of the entity.

1.15 "API Compound" means bulk quantities of Compound prior to the

-----

commencement of secondary manufacturing resulting in a Collaboration Product.

1.16 "API Compound Carrying Cost" means \*\* percent (\*\*%) of the

-----

dollar amount obtained by multiplying the average dollar value of API Compound in a Calendar Quarter held in inventory by a Party for use in Development or Commercialization of Collaboration Products by \*\* percent (\*\*%).

1.17 "Applicable Committee" shall have the meaning set forth in

-----

Section 12.3.

1.18 "Auditing Party" shall have the meaning set forth in Section

-----

6.14.

1.19 "Breaching Party" shall have the meaning set forth in Section

-----

16.3.

1.20 "Business Day" means any day on which banking institutions in

-----

both New York, New York, United States and London, England are open for business

1.21 "Calendar Quarter" means for each Calendar Year, each of the

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three month periods ending March 31, June 30, September 30 and December 31; provided, however, that the first calendar quarter for the first Calendar Year shall extend from the Effective Date to the end of the first complete calendar quarter thereafter.

1.22 "Calendar Year" means, for the first calendar year, the period

-----

commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.

1.23 "Call" means a personal visit by a Sales Representative to a

----

member of the Target Audience legally permitted to prescribe prescription drugs in the United States during which such Sales Representative Details a Collaboration Product. The Parties may, by mutual agreement, designate additional types of Calls.

1.24 "Claims" means all charges, complaints, actions, suits,

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proceedings, hearings, investigations, claims and demands.

1.25 "Collaboration Products" means the Adolor Products and the GI

-----

Products.

1.26 "\*\*\* Product" shall have the meaning set forth in Section \*\*.

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\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.27 "Commercialization" means any and all activities directed to

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marketing, promoting, distributing, offering for sale and selling a Collaboration Product, importing a Collaboration Product (to the extent applicable) and conducting Phase IV Studies, including, without limitation and where applicable, Co-Promoting. When used as a verb, "Commercialize" means to

-----

engage in Commercialization.

1.28 \*\*

1.29 "Compound" means the peripheral mu antagonist having molecular

-----

formula(+)-[[2(S)-[[4(R)-(3-hydroxyphenyl)-3(R),4-dimethyl-1-piperidiny]-  
methyl]-1-oxo-3-phenylpropyl]amino]acetic acid dihydrate, known generically as  
"alvimopan", and all pharmaceutically acceptable salts and solvates thereof.

1.30 "Confidential Information" means all secret, confidential or

-----  
proprietary information or data, whether provided in written, oral, graphic,  
video, computer or other form, provided by one Party (the "Disclosing Party") to

-----  
the other Party (the "Receiving Party") pursuant to this Agreement or generated

-----  
pursuant to this Agreement, including but not limited to, information relating  
to the Disclosing Party's existing or proposed research, development efforts,  
patent applications, business or products, the terms of this Agreement and any  
other materials that have not been made available by the Disclosing Party to the  
general public. Notwithstanding the foregoing sentence, Confidential Information  
shall not include any information or materials that:

1.30.1 were already known to the Receiving Party (other than under  
an obligation of confidentiality), at the time of disclosure by the Disclosing  
Party to the extent such Receiving Party has documentary evidence to that  
effect;

1.30.2 were generally available to the public or otherwise part of  
the public domain at the time of its disclosure to the Receiving Party;

1.30.3 became generally available to the public or otherwise part  
of the public domain after its disclosure or development, as the case may be,  
and other than through any act or omission of a Party in breach of such Party's  
confidentiality obligations under this Agreement;

1.30.4 were disclosed to a Party, other than under an obligation  
of confidentiality, by a Third Party who had no obligation to the Disclosing  
Party not to disclose such information to others; or

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the Commission. Confidential treatment has been requested with respect to the  
omitted portions.

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1.30.5 were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party and the Receiving Party has documentary evidence to that effect.

1.31 "\*\*\* Product" means a Product for the management of non-opioid

-----

induced forms of \*\* or \*\* which such Product is not an \*\* Product.

1.32 "Co-Promotion" means those promotional activities undertaken by a

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pharmaceutical company's sales force in concert with at least one other pharmaceutical company's sales force to implement the marketing plans and strategies with respect to a particular prescription pharmaceutical product under a single trademark. When used as a verb, "Co-Promote" shall mean to engage

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in such activities.

1.33 "Cost of Goods" means the total cost of API Compound and/or a

-----

Collaboration Product (in formulated and/or finished packaged and labeled form) as invoiced by Third Parties, including without limitation the sum of the following actual costs: \*\*. In the event that GSK manufactures API Compound and/or Collaboration Products pursuant to Article 10, Cost of Goods shall be calculated in accordance with Schedule 1.33.

-----

1.34 "Country" means any generally recognized sovereign entity.

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1.35 "CRO(s)" shall have the meaning set forth in Section 2.3.2(b).

-----

1.36 "Defaulting Party" shall have the meaning set forth in Section

-----

6.3.4.

1.37 "Designated Foreign Filing" shall have the meaning set forth in

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Section 15.1.2(b).

1.38 "Detail" or "Detailing" means, with respect to a Collaboration

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Product, the communication by a Sales Representative during a Call to a member of the Target Audience (a) involving face-to-face contact, (b) describing in a fair and balanced manner the FDA-approved indicated uses and other relevant characteristics of such Collaboration Product, (c) using the Promotional Materials in an effort to increase the Target Audience prescribing and/or hospital ordering preferences of a Collaboration Product for its FDA-approved indicated uses, and (d) made at the Target Audience member's office, in a hospital, at marketing meetings sponsored by a Party for the Collaboration Products or other appropriate venues conducive to pharmaceutical product informational communication where the principal objective is to place an emphasis, either primary or secondary, on a Collaboration Product and not simply to discuss a Collaboration Product with a member of the Target Audience. For the avoidance of doubt, discussions at conventions shall not constitute "Details" or "Detailing".

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1.39 "Detail Cost" means, unless otherwise agreed to by the Parties, \*\*

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dollars (\$\*\*) for each Major Detail, \*\* dollars (\$\*\*) for each Secondary Detail and \*\* dollars (\$\*\*) if such Detail was conducted by a Specialist Sales Representative, in each case adjusted for inflation beginning with respect to Calendar Year beginning January 1, 2003, using the Producer Price Index as published by the Bureau of Labor Statistics of the U.S. Department of Labor.

1.40 "Detail Requirements" shall have the meaning set forth in Section 5.7.

-----

1.41 "Development" or "Develop" means preclinical and clinical drug

-----

development activities, including, among other things: test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, current Good

Manufacturing Practices audits, current Good Clinical Practices audits, current Good Laboratory Practices audits, analytical method validation, manufacturing process validation, cleaning validation, scale-up and post approval changes, quality assurance/quality control development, statistical analysis and report writing, preclinical and clinical studies, including, without limitation, \*\*, regulatory filing submission and approval, and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in Development. For

-----

clarity, Development does not include \*\*.

1.42 "Development Expenses" means, for all studies or activities performed

-----

by or on behalf of either Party or any of its Affiliates to the extent provided for in an approved U.S. Development Plan or otherwise approved in advance by the Joint Development Committee or Joint Steering Committee, including without limitation Phase III Studies, that are relevant to the Development of Collaboration Products for Commercialization in the \*\*:

1.42.1 \*\* costs and expenses incurred (i.e., paid or accrued) to a \*\*, in connection with all Development activities performed in accordance with the U.S. Development Plan;

1.42.2 the cost of clinical supplies for such studies or activities as agreed in the U.S. Development Plan, which costs shall be comprised of (i) the cost of clinical and pre-clinical supplies, including Compound, utilized in Development, (ii) out-of-pocket costs and expenses incurred in purchasing comparator drug and in packaging comparator drug and/or the Collaboration Products, shipping clinical supplies to centers or disposal of clinical supplies, and (iii) actual costs of packaging comparator if done by a Party.

It is understood and agreed that development expenses relating to the Collaboration Products in the United States incurred by Adolor after \*\* and prior to the formation of the Joint Development Committee and the Joint Steering Committee shall be included as Development Expenses.

1.43 "Development Milestone" shall have the meaning set forth in Section

-----

6.2.1.

1.44 "Disclosing Party" shall have the meaning set forth in Section 1.30.

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1.45 "Dispute Detailing Audit Data" means the absolute number of Details

-----

performed by a Party's Sales Representatives for a given Calendar Year, as reflected in the Personal Selling Audit and Hospital Personal Selling Audit of Scott-Levin Associates or IMS America. In the event the Personal Selling Audit or Hospital Personal Selling Audit for any given period or periods does not report details for the physician specialties which correspond to the Target Audience, the Parties shall mutually agree upon an alternative methodology to verify the internal Detailing records of a Party.

1.46 "Distribution Services Fee" shall have the meaning set forth in

-----

Section 6.3.3.

1.47 "Exchange Act" shall have the meaning set forth in Section 17.1.1.

-----

1.48 "FDA" means the United States Food and Drug Administration and any

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successor agency thereto.

1.49 "Field" means all uses of Compound in human beings except in products

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or formulations containing \*\*.

1.50 "First Commercial Sale" means the first shipment of commercial

-----

quantities of any Collaboration Product sold to a Third Party by a Party or its sublicensees in any Country after receipt of Marketing Authorization Approval for such Collaboration Product in such Country. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar uses shall not be considered to constitute a First Commercial Sale.

1.51 "Force Majeure Event" shall have the meaning set forth in Section

-----

18.3.

1.52 "Generic Competition" means, on a Country-by-Country basis and

-----

Collaboration Product-by-Collaboration Product basis, the presence of a drug product that contains the same active ingredient as the Collaboration Product (inactive ingredients may vary), is identical to the Collaboration Product in strength, dosage form and route of administration, is bioequivalent to the Collaboration Product and is approved by the relevant Governmental Authority in such Country and which has obtained sales greater than \*\* (\*\*%) of the combined sales of such Collaboration Product together with such generic drug products, \*\*, in any Calendar Quarter, and which generic drug product sales are evidenced by independent market data (where available), such as that published by IMS.

1.53 "GI Product" means an OBD Chronic Product, a \*\* Product, an \*\*

-----

Product, or any Additional Product designated by the Parties as a GI Product pursuant to Section 4.3.

1.54 "GI Product Marketing Contribution" means an amount equal to Net Sales

-----

for GI Products in the applicable reporting period in the United States less the following amounts: (a) \*\* of the GI Product constituting such \*\*; (b) the \*\*; (c) royalties paid to \*\* on account of sales of \*\* Products in the United States; (d) \*\*; and (e) \*\* for such \*\* Product.

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.55 "GI Product Promotion Term" means, on a GI Product-by-GI Product

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basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of a Patent Right covering such GI Product in the United States, (b) \*\* (\*\*) years from First Commercial Sale in the United States, and (c) the existence of Generic Competition for \*\* for such



GI Product in the United States.

1.56 "GI Product Trademarks" shall have the meaning set forth in Section

-----

2.4.2.

1.57 "Governmental Authority" means any court, tribunal, arbitrator,

-----

agency, legislative body, commission, official or other instrumentality of (i)  
any government of any Country, (ii) a federal, state, province, county, city or  
other political subdivision thereof or (iii) any supranational body, including  
without limitation the European Agency for the Evaluation of Medicinal Products.

1.58 "GSK Housemark" means the name and logo of GSK or an Affiliate of GSK

-----

as identified by GSK to Adolor from time to time.

1.59 "GSK Invention" means an Invention that is conceived or reduced to

-----

practice by an employee or agent of GSK solely or jointly with a Third Party.

1.60 "GSK Know-How" means all present and future Know-How that relates to

-----

the Collaboration Products, the Compound or the GSK Inventions, to the extent  
necessary for Adolor to perform its obligations or enjoy its rights under this  
Agreement, and which during the Term are in GSK's or any of its Affiliates'  
possession or control and are or become owned by, or otherwise may be licensed  
by, GSK. GSK Know-How does not include any GSK Patents.

1.61 "GSK Other GI Product" shall have the meaning set forth in Section

-----

4.3.3(b).

1.62 "GSK Patent" means all Patent Rights covering the Collaboration

-----

Products, the Compound or the GSK Inventions which are or become owned by GSK or  
GSK's Affiliates, or as to which GSK or GSK's Affiliates otherwise are or become  
licensed, now or in the future, with the right to grant the sublicense rights  
granted to Adolor under this Agreement, which Patent Rights cover the making,  
having made, use, offer for sale, sale or importation of the Collaboration  
Products or the Compound.

1.63 "GSK Product" shall have the meaning set forth in Section 11.1.

-----

1.64 "GSK Product Agreement" shall have the meaning set forth in Section

-----

11.2.2.

1.65 "GSK Product Selection Period" shall have the meaning set forth in

-----

Section 11.2.3.

1.66 "GSK Reconciliation Report" shall have the meaning set forth in

-----

Section 6.7.5(b).

1.67 "GSK Report" shall have the meaning set forth in Section 6.7.2.

-----

1.68 "Hatch-Waxman Certification" shall have the meaning set forth in

-----

Section 15.3.

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1.69 "Hostile Tender Offer" shall have the meaning set forth in Section

-----

17.2.5.

1.70 "HSR Act" shall have the meaning set forth in Section 13.2.6.

-----

1.71 "\*\*\* Product" means a Product for the management of \*\* which such

-----

Product is not a \*\* Product.

1.72 "Indemnified Party" shall have the meaning set forth in Section

-----

14.3.1.

1.73 "Indemnifying Party" shall have the meaning set forth in Section

-----

14.3.1.

1.74 "Initial Incentive Period" shall have the meaning set forth in Section

-----

5.8.

1.75 "Initial \*\* Year Period" shall have the meaning set forth in Section

-----

6.3.1.

1.76 "Internal Detailing Report" shall have the meaning set forth in

-----

Section 5.9.1.

1.77 "Invention" means any discovery (whether patentable or not) conceived

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or reduced to practice during the Term as a result of the Development or Commercialization activities and related to, derived from or useful for the manufacture, use or sale of the Compound or a Collaboration Product.

1.78 "Investigational Authorization" means, with respect to a Country, the

-----

regulatory authorization required to investigate a Collaboration Product in such Country as granted by the relevant Governmental Authority.

1.79 "Joint Development Committee" shall have the meaning set forth in

-----

Section 3.2.1.

1.80 "Joint Invention" means an Invention that is conceived or reduced to

-----

practice jointly by employees and/or agents of both Adolor and GSK.

1.81 "Joint Marketing Committee" shall have the meaning set forth in

-----

Section 3.3.1.

1.82 "Joint Supply Committee" shall have the meaning set forth in Section

-----

3.4.1.

1.83 "Joint Steering Committee" shall have the meaning set forth in Section

-----

3.1.1.

1.84 "Know-How" means any technical information, know-how and materials,

-----

including without limitation all biological, chemical, pharmacological, toxicological, clinical, assay and other information, data, discoveries, inventions, improvements, processes, formulae and trade secrets, patentable or otherwise.

1.85 "Laws" means all laws, statutes, rules, regulations (including,

----

without limitation, current Good Manufacturing Practice Regulations as specified in 21 C.F.R. (S)(S) 210 and 211; Investigational New Drug Application regulations at 21 C.F.R. (S) 312; NDA regulations at 21 C.F.R. (S) 314, relevant provisions of the Federal Food, Drug and Cosmetic Act, and other laws and regulations enforced by the FDA), ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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<PAGE>

1.86 "Lilly" means Eli Lilly and Company and its successors and permitted

-----

assigns.

1.87 "Litigation Condition" shall have the meaning set forth in Section

-----

14.3.2.

1.88 "Losses" means any and all damages (including all incidental,

-----

consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including without limitation court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any

settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

1.89 "Major Detail" means a Detail for a Collaboration Product in which

-----

such Collaboration Product receives the predominant portion of emphasis and time during the Call (i.e., no other product receives more emphasis or time during the Call).

1.90 "Major Market Country" means each of \*\* and \*\*.

-----

1.91 "Major Region" means the Country or Countries in each of the following

-----

geographic regions: \*\*.

1.92 "Marketing Authorization" means, with respect to a Country, the

-----

regulatory authorization required to market and sell a Collaboration Product in such Country as granted by the relevant Governmental Authority.

1.93 "Marketing Authorization Approval" shall mean approval by a

-----

Governmental Authority for sale of a Collaboration Product, including any applicable pricing, final labeling or reimbursement approvals.

1.94 "Marketing Expenses" means, excluding any Development Expenses, all

-----

\*\* costs and expenses incurred (i.e., paid or accrued) to a \*\*, whether

---

incurred by Adolor or its Affiliates, or GSK or its Affiliates, to the extent provided for in an approved U.S. Marketing Plan or otherwise approved in advance by the Joint Marketing Committee or the Joint Steering Committee, and solely to the extent related to Collaboration Products, for Commercialization in the United States in connection with:

1.94.1 Marketing, advertising, sampling and promoting a Collaboration Product, including without limitation educational expenses, speakers' programs and symposia, and joint marketing and sales meetings in accordance with Section

5.10.4, but excluding \*\* unless otherwise mutually agreed by the Parties;

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1.94.2 \*\*;

1.94.3 Primary and secondary market research;

1.94.4 Promotional Materials; and

1.94.5 Samples (at Cost of Goods) distributed in the United States.

It is understood and agreed that marketing expenses relating to the Collaboration Products in the United States incurred by Adolor after \*\* and prior to the formation of the Joint Marketing Committee and the Joint Steering Committee shall be included as Marketing Expenses but Marketing Expenses shall not include any: (a) costs associated with distribution of Collaboration Products to be provided by GSK pursuant to Section 5.5.2(b); or (b) costs or expenses incurred by a Party for services that are performed by a Third Party if such services are of a type that are normally performed by \*\* unless the Joint Marketing Committee has designated such services be performed by external personnel consistent with quality and timeliness objectives. It is further understood and agreed that Marketing Expenses shall not include the costs or expenses incurred by a Party for performance of its Detailing obligations under Article 5.

1.95 "NDA" means a new drug application or supplemental new drug

---

application or any amendments thereto submitted to the FDA in the United States.

1.96 "NDA Acceptance" shall mean the written notification by the FDA

-----

that the NDA has met all the criteria for filing acceptance pursuant to 21

C.F.R.(S)314.101.

1.97 \*\*

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the

omitted portions.

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\*\*

1.98 "Net Sales Report" shall have the meaning set forth in Section

-----

6.6.2.

1.99 "OBD Acute Product" means a Product for the management of opioid

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induced bowel dysfunction in hospitalized patients or patients discharged from a  
hospital for whom prescriptions or \*\*.

1.100 "OBD Chronic Product" means a Product for the management of

-----

patients with bowel dysfunction caused by the \*\* administration of opioids.

1.101 "Officers" shall have the meaning set forth in Section 3.1.4(b).

-----

1.102 "OTC" means the over-the-counter, non-prescription market as

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opposed to prescription sales.

1.103 "Patent Infringement Claim" shall have the meaning set forth in

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Section 15.2.1.

1.104 "Patent Infringement Notice" shall have the meaning set forth in

-----

Section 15.2.2.

1.105 "Patent Rights" means all existing patents and patent

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applications and all patent applications hereafter filed, including any  
continuations, continuations-in-part, divisions, provisionals or any substitute  
applications, any patent issued with respect to any such patent applications,  
any reissue, reexamination, renewal or extension (including any supplementary  
protection certificate) of any such patent, and any confirmation patent or  
registration patent or patent of addition based on any such patent, and all  
foreign counterparts of any of the foregoing, or as applicable portions thereof

or individual claims therein.

1.106 "PDM Act" shall have the meaning set forth in Section 7.2.3.

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\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.107 "Person" means any natural person, corporation, general

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partnership, limited partnership, joint venture, proprietorship or other business organization.

1.108 "Pharmacovigilance Agreement" means the Pharmacovigilance and

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Global Safety Reporting Agreement to be entered into by the Parties pursuant to Section 9.6.

1.109 "Phase I Studies" means that portion of the U.S. Development

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Plan, ROW Development Plan or Development relating to each Collaboration Product which provides for the first introduction into humans of such Collaboration Product including small scale clinical studies conducted in normal volunteers or patients to obtain information on such Collaboration Product's safety, tolerability, pharmacological activity, pharmacokinetics, drug metabolism and mechanism of action, as well as early evidence of effectiveness, as more fully defined in 21 C.F.R. (S) 312.21(a).

1.110 "Phase II Studies" means that portion of the clinical U.S.

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Development Plan, ROW Development Plan or Development relating to each Collaboration Product which provides for well controlled clinical trials of such Collaboration Product in patients, including clinical studies conducted in patients with the condition, and designed to evaluate clinical efficacy and safety for such Collaboration Product for one or more indications, as well as to obtain an indication of the dosage regimen required, as more fully defined in 21 C.F.R. (S) 312.21(b).



1.111 "Phase III Studies" means that portion of the clinical U.S.

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Development Plan, ROW Development Plan or Development relating to each Collaboration Product which provides for large scale, pivotal, clinical studies conducted in a sufficient number of patients and whose primary objective is to obtain a definitive evaluation of the therapeutic efficacy and safety of the Collaboration Product in patients for the particular indication in question that is needed to evaluate the overall risk-benefit relationship of Collaboration Product and to provide adequate basis for obtaining requisite regulatory approval(s) and product labeling, as more fully defined in 21 C.F.R. (S) 312.21(c).

1.112 "Phase IV Studies" means a study for a Collaboration Product that

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is initiated in a Country after receipt of a Marketing Authorization for a Collaboration Product in the United States and which is expected to be completed with respect to an Adolor Product during the Adolor Product Promotion Term and with respect to a GI Product during the GI Product Promotion Term and is principally intended to support the marketing and Commercialization of such Collaboration Product in the United States, including without limitation investigator initiated trials, clinical experience trials and studies conducted to fulfill local commitments made as a condition of any Marketing Authorization.

1.113 "POI Contract Product Profile" means the contract product profile

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for the POI Product attached hereto as Schedule 1.113.

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1.114 "POI Product" means a Product for the prevention, treatment or

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management of post-operative ileus or post-operative bowel dysfunction.

1.115 "\*\*\* Product" means a Product for the management of \*\* or \*\*.

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\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.116 "Product" means a prescription pharmaceutical product that

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contains Compound as the sole active ingredient for use in the Field. For the avoidance of doubt, Product shall not include products sold in the OTC market.

1.117 "Product Liability Claim" shall have the meaning set forth in

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Section 14.5.1.

1.118 "Product Supplier" means any manufacturer, packager or processor

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of Compound or a Collaboration Product for development, promotion and sale.

1.119 "Promotional Materials" means all written, printed, video or

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graphic advertising, promotional, educational and communication materials (other than Collaboration Product labeling) for marketing, advertising and promotion of the Collaboration Products for use in the United States by (a) a Sales Representative or (b) advertisements or direct mail pieces, in accordance with the terms of the applicable U.S. Marketing Plan.

1.120 "Receiving Party" shall have the meaning set forth in Section

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1.30.

1.121 "Recording Party" shall have the meaning set forth in Section

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6.14.

1.122 "ROW" means Countries other than the United States.

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1.123 "ROW Development Plan" shall have the meaning set forth in

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Section 4.7.2.

1.124 "ROW Net Sales Forecast" shall have the meaning set forth in

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Section 5.11.2(c).

1.125 "ROW Term" means, on a Country-by-Country and Collaboration

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Product-by-Collaboration Product basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of a Patent Right covering such Collaboration Product in such Country, (b) \*\* (\*\*) years from First Commercial Sale in such Country, and (c) the existence of Generic Competition for \*\* for such Collaboration Product in such Country.

1.126 "ROW Trademarks" shall have the meaning set forth in Section

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2.4.3.

1.127 "Royalty Conversion Election" shall have the meaning set forth in

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Section 6.3.5.

1.128 "Sales Representative" means a professional pharmaceutical sales

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representative engaged or employed by either Party to conduct, among other sales responsibilities, Detailing and other promotional efforts with respect to the Collaboration Products and who has been trained by either Party in accordance with a training protocol to be agreed upon by the Parties.

1.129 "Samples" means Collaboration Product packaged and distributed to

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members of the Target Audience as a complementary trial for use with patients in the United States and in accordance with the PDM Act.

1.130 "SEC" shall have the meaning set forth in Section 17.1.2.

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\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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1.131 "Secondary Detail" means a Detail for a Collaboration Product in

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which such Collaboration Product receives the second most emphasis and time during the Call (i.e., at most, only one other product receives greater emphasis and time during the Call).

1.132 "Selected GSK Product" shall have the meaning set forth in

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Section 11.2.2.

1.133 "Shire" means Shire Pharmaceuticals Group plc and its successors

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and permitted assigns.

1.134 "Specialist Sales Representative" means a Sales Representative

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who has specialist skills and/or knowledge in relation to the practice areas of some or all of those physician groups which make up the Target Audience and who, as a result of such skills and/or knowledge, has as one of his or her principal functions the promotion of pharmaceutical products to such physician groups.

1.135 "Standard Terms" shall have the meaning set forth in Section

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10.6.4.

1.136 "Target Audience" means (a) for the POI Product, the physician

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specialties set forth on Schedule 1.136 with authority to prescribe a

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pharmaceutical product or issue hospital orders for a pharmaceutical product in the United States, and (b) for each other Collaboration Product, the physician specialties identified in the U.S. Marketing Plan for such Collaboration Product, in each case as may be amended from time to time by the Joint Marketing Committee.

1.137 "Taxes" shall have the meaning set forth in Section 6.13.

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1.138 "Term" means the longer of the United States Term and the ROW

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Term.

1.139 "Terminated Collaboration Product" shall have the meaning set

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forth in Section 16.12.

1.140 "Testing Protocol" shall have the meaning set forth in Section

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3.4.2(a).

1.141 "Third Party" means a Person who is not a Party or an Affiliate

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of a Party.

1.142 "Third Party Claim" shall have the meaning set forth in Section

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14.3.1.

1.143 "Trademark Infringement Claim" shall have the meaning set forth

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in Section 2.4.8(a).

1.144 "Trademark Infringement Notice" shall have the meaning set forth

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in Section 2.4.8(b).

1.145 "United States" means the United States, its territories and

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possessions.

1.146 "U.S. Development Plan" means the plan for each Collaboration

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Product designed to achieve the Development for such Collaboration Product for the United States, including, without limitation, the budget and nature, number and schedule of Development activities. The initial U.S. Development Plans for the POI Product and the OBD Chronic Product are attached hereto as Schedule

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1.146, and as they may be amended in accordance with the terms of this

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Agreement.

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1.147 "U.S. Marketing Plan" means for each Collaboration Product a plan

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and budget for the promotion and marketing of the Collaboration Products in the United States as developed and approved under Section 5.1.

1.148 "United States Term" means the longer of the Adolor Product

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Promotion Term and the GI Product Promotion Term.

1.149 "Valid Claim" means any claim of a pending patent application

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which has not been abandoned or finally rejected without the right of appeal or which is not knowingly patentable, or any claim from an issued and unexpired patent included within the Patent Rights which has not been revoked or held unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.150 "Withholding Party" shall have the meaning set forth in Section

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6.13.

## ARTICLE 2

### RIGHTS AND OBLIGATIONS

#### 2.1 License Grants from Adolor to GSK.

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##### 2.1.1 United States Development License. Subject to the terms of

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this Agreement, Adolor grants to GSK, and GSK accepts, an exclusive (except as to Adolor and its Affiliates) and non-transferable (except in accordance with Section 2.3) license under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint Inventions (a) during the Adolor Product Promotion Term, to use and Develop Adolor Products for Commercialization in the United States, and (b) during the GI Product Promotion Term, to make, have made (subject to Section 2.3), use and Develop GI Products for Commercialization in the United States. In the event the Parties agree pursuant to Article 10 that GSK will manufacture Adolor Products for sale in the United States, the license grant in Section 2.1.1(a) shall also include rights to make and have made (subject to Section 2.3) Adolor Products in the United States.

##### 2.1.2 ROW Development License. Subject to the terms of this

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Agreement, during the ROW Term, Adolor grants to GSK, and GSK accepts, an exclusive and non-transferable (except in accordance with Section 2.3) license under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint

Inventions to make, have made (subject to Section 2.3), use and Develop

Collaboration Products for Commercialization in the ROW.

2.1.3 United States Co-Promotion Rights. Subject to the terms of

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this Agreement, Adolor grants to GSK, and GSK accepts, an exclusive (except as to Adolor and its Affiliates) and non-transferable (except in accordance with Section 2.3) right under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint Inventions to Co-Promote (a) during the Adolor Product Promotion Term, Adolor Products with Adolor in the United States, and (b) during the GI Product

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Promotion Term, OBD Chronic Product, and other GI Products where Adolor has elected to fund Development under Section 4.6.5 and where Adolor has not made a Royalty Conversion Election, with Adolor in the United States.

2.1.4 Commercialization License in United States. Subject to the

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terms of this Agreement, and in addition to the Co-Promotion rights granted under Section 2.1.3, during the GI Product Promotion Term, Adolor hereby grants to GSK, and GSK accepts, an exclusive (except as to Adolor and its Affiliates) and non-transferable (except in accordance with Section 2.3) license under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint Inventions to make, have made (subject to Section 2.3), use, sell, offer for sale and import GI Products in the United States.

2.1.5 Commercialization License in ROW. Subject to the terms of

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this Agreement, during the ROW Term, Adolor hereby grants to GSK, and GSK accepts, an exclusive and non-transferable (except in accordance with Section 2.3) license under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint Inventions to make, have made (subject to Section 2.3), use, sell, offer for sale and import Collaboration Products in the ROW.

2.1.6 Manufacturing License in the Event of a Shortage. In the

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event that GSK assumes manufacturing responsibility in accordance with Section

10.9, Adolor, subject to the terms of this Agreement, grants to GSK a non-exclusive and non-transferable (except in accordance with Section 2.3) license under the Adolor Patents, Adolor Know-How and Adolor's rights in the Joint Inventions to make and have made API Compound or formulated Collaboration Product.

2.1.7 \*\* Products. Subject to the terms of this Agreement, Adolor

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retains the exclusive right to develop, make, use, import, distribute, sell, offer for sale and have sold products containing \*\*.

2.2 License Grant from GSK to Adolor. Subject to the terms of this

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Agreement, GSK grants to Adolor, and Adolor accepts, an exclusive (except as to GSK and its Affiliates), irrevocable, non-transferable (except in accordance with Section 2.3) \*\* license under the GSK Patents, GSK Know-How and GSK's rights in the Joint Inventions (a) at all times during \*\* the Adolor Product Promotion Term, to make, have made, use, sell, have sold, offer for sale and import Adolor Products in the United States, (b) during the GI Product Promotion Term, for the OBD Chronic Product and, where Adolor has elected to fund Development of another GI Product under Section 4.6.5 and in each case where Adolor has not made a Royalty Conversion Election, to Co-Promote the OBD Chronic Product and such other GI Products in the United States, (c) \*\*, to make, have made, use, sell, have sold, offer for sale and import GI Products in the United States, (d) \*\*, to make, have made, use, sell, have sold, offer for sale

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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and import such Collaboration Product in such Country in the ROW, and (e)\*\* , to make, have made, use, sell, offer for sale, have sold and import, Combination Products and Compound in all Countries of the world.

2.3 Sublicensing and Subcontracting. Subject to this Section 2.3,

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neither Party may sublicense or subcontract its rights under this Agreement to



an Affiliate or a Third Party without the prior written consent of the other Party.

#### 2.3.1 GSK Sublicensing or Subcontracting to Affiliates. GSK may

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sublicense or subcontract its rights to Develop or Commercialize in whole or in part to one or more of its Affiliates, provided that the rights sublicensed or subcontracted to such Affiliate shall automatically terminate upon a change of control of such Affiliate in connection with which such Affiliate ceases to be an Affiliate of GSK.

#### 2.3.2 GSK Sublicensing or Subcontracting to Third Parties.

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(a) With respect to the Major Market Countries, GSK shall be prohibited from sublicensing or subcontracting to any Third Party any of GSK's rights to Commercialize the Collaboration Products without the prior written consent of Adolor, such consent not to be unreasonably withheld or delayed. With respect to all Countries of the \*\*, GSK shall be entitled to sublicense or subcontract to any Third Party any of GSK's rights to Commercialize the Collaboration Products on a Country-by-Country basis to the extent and only to the extent where such activity is in accordance with GSK's usual business practices as applied in such Country.

(b) If set forth in an agreed upon U.S. Development Plan or U.S. Marketing Plan, or in GSK's discretion with respect to the ROW, GSK shall be permitted to subcontract its Development activities or Phase IV Studies to one or more Third Party contract research organizations ("CRO(s)"), or equivalent

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Third Party entities, to carry out certain Development activities on behalf of GSK in relation to any Collaboration Product under this Agreement and, for the avoidance of doubt, such CRO or equivalent Third Party entities shall not be considered a sublicensee for the purposes of this Section 2.3.

#### 2.3.3 Adolor Sublicensing or Subcontracting to Affiliates. Adolor may

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sublicense or subcontract its responsibilities to be performed under this Agreement in whole or in part to one or more of its Affiliates, provided that the rights sublicensed or subcontracted to such Affiliate shall automatically

terminate upon a change of control of such Affiliate in connection with which such Affiliate ceases to be an Affiliate of Adolor.

#### 2.3.4 Adolor Sublicensing or Subcontracting to Third Parties. If set

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forth in the applicable U.S. Development Plan or U.S. Marketing Plan, Adolor may sublicense or subcontract its Development or Commercialization activities (other  
\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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than Detailing except as provided in this Section 2.3.4) to a Third Party. The Parties agree that Adolor may request that GSK provide Sales Representatives to perform Adolor's Details of Collaboration Products. In the event that GSK provides such Sales Representatives, the related costs of and/or remuneration for such Details so performed by GSK shall be agreed in good faith by the Parties at such time, taking into account both the prevailing Detail Cost and the cost of Details that could be provided by a Third Party contract sales organization (whose primary business is to detail pharmaceutical products on behalf of another party) for comparable number of Details and Sales Representatives; provided that if GSK performs such Details, Adolor shall not be considered a Defaulting Party and there shall be no adjustment pursuant to Section 6.3.4. In the event that GSK does not provide such Sales Representatives, Adolor may engage a contract sales organization (whose primary business is to detail pharmaceutical products on behalf of another party) to perform such Details. In addition, it is understood that Adolor may utilize a contract sales organization (whose primary business is to detail pharmaceutical products on behalf of another party) to recruit Sales Representatives for Adolor.

#### 2.3.5 Liability for Affiliates, Sublicensees and Subcontractors. Each

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Party shall ensure that each of its Affiliates and permitted sublicensees or subcontractors accepts and complies with all of the terms and conditions of this Agreement as if such Affiliates or permitted sublicensees or subcontractors were

a party to this Agreement and each Party shall guarantee its Affiliates' and permitted sublicensees' or subcontractors' performance under this Agreement.

#### 2.4 Trademarks and Housemarks.

##### 2.4.1 United States Trademarks for Adolor Products; Adolor Trade

Dress. The Adolor Products shall be Commercialized in the United States under

trademarks and trade dress selected by the Joint Marketing Committee and approved by the Joint Steering Committee (the "Adolor Product Trademarks"). It

is understood that Adolor has submitted to the FDA for consideration the trademarks "Entereg" and "Alvanop" for possible use with the POI Product. If the Joint Marketing Committee or the Joint Steering Committee selects a GI Product Trademark for use in connection with an Adolor Product in the United States, GSK shall license such GI Product Trademark for use by Adolor in connection with the Commercialization of such Adolor Product in the United States, in which case such GI Product Trademark will remain a GI Product Trademark and will not be deemed an Adolor Product Trademark. The Adolor Product Trademarks shall be owned by Adolor and GSK agrees to assign any rights it may have in the Adolor Product Trademarks to Adolor. GSK shall have no rights under this Agreement in or to the Adolor Product Trademarks or the goodwill pertaining thereto except as specifically provided herein. GSK and its Affiliates shall utilize the Adolor Product Trademarks only for the purposes contemplated herein. GSK agrees that upon termination or expiration of the Adolor Product Promotion Term, it will discontinue forthwith all use of the Adolor Product Trademarks except for permitted use in the United States with a GI Product in the United States as set

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forth in the license grant at Section 2.4.2 or with a Collaboration Product in the ROW under its assigned rights in the ROW as set forth in Section 2.4.3. Subject to Sections 16.10.2 and 16.11.2, to the extent Adolor licenses any of its intellectual property to GSK under this Agreement for trade dress purposes GSK acknowledges that nothing in this Agreement shall give it any right, title

or interest in such intellectual property.

#### 2.4.2 United States Trademarks for GI Products; GSK Trade Dress.

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The GI Products shall be Commercialized in the United States under trademarks and trade dress selected by the Joint Marketing Committee and approved by the Joint Steering Committee (the "GI Product Trademarks"). If an Adolor Product

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Trademark is so selected for use with a GI Product in the United States, Adolor shall license such Adolor Product Trademark for use by GSK in connection with the Commercialization of such GI Product in the United States, in which case such Adolor Product Trademark will remain an Adolor Product Trademark and will not be deemed a GI Product Trademark. The GI Product Trademarks shall be owned by GSK and Adolor agrees to assign any rights it may have in the GI Product Trademarks to GSK. Adolor shall have no rights under this Agreement in or to the GI Product Trademarks or the goodwill pertaining thereto except as specifically provided herein. Adolor and its Affiliates shall utilize the GI Product Trademarks only for the purposes contemplated herein. Adolor agrees that upon termination or expiration of the GI Product Promotion Term, it will discontinue forthwith all use of the GI Product Trademarks with the GI Products, except in the event a GI Product Trademark is assigned to Adolor pursuant to Section 16.10.4 or 16.12.4 or in the event that a GI Product Trademark is used in connection with another GI Product or an Adolor Product in the United States pursuant to Section 2.4.1. Subject to Sections 16.9.5, 16.10.4 and 16.12.4, to the extent GSK licenses any of its intellectual property to Adolor under this Agreement for trade dress purposes, Adolor acknowledges that nothing in this Agreement shall give it any right, title or interest in such intellectual property.

#### 2.4.3 ROW Trademarks. The Collaboration Products shall be

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Commercialized in the ROW under trademarks and trade dress selected by GSK (the "ROW Trademarks"). GSK may select an Adolor Product Trademark or a GI Product

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Trademark for use in connection with a Collaboration Product in the ROW, provided that GSK shall use its Commercially Reasonable Efforts to ensure that

such use is consistent with the use of such Adolor Product Trademark or GI Product Trademark in the United States in connection with Collaboration Products. In such case Adolor shall promptly take all steps necessary, at the expense and direction of GSK, to assign the Adolor Product Trademarks for the Country or Countries in the ROW for which GSK notifies Adolor it wishes to utilize such Adolor Product Trademark in connection with such Collaboration Product. After such assignment has been effected, the Adolor Product Trademark to be used in such Country or Countries shall be deemed a ROW Trademark. Adolor shall have no rights under this Agreement in or to the ROW Trademarks or the goodwill pertaining thereto except as specifically provided herein.

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#### 2.4.4 Trademark and Housemark Licenses.

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(a) Adolor hereby grants to GSK (i) a non-exclusive, non-transferable (except in accordance with Section 2.3) license to use the Adolor Housemark in the United States during the Adolor Product Promotion Term solely in conjunction with the Adolor Products, (ii) an exclusive (except as to Adolor and its Affiliates), non-transferable (except in accordance with Section 2.3) license to use the Adolor Product Trademarks in the United States during the Adolor Product Promotion Term solely in conjunction with the Adolor Products, (iii) a non-exclusive, non-transferable (except in accordance with Section 2.3) license to use the Adolor Housemark in the United States during the GI Product Promotion Term solely in conjunction with the GI Products, (iv) an exclusive (except as to Adolor and its Affiliates), non-transferable (except in accordance with Section 2.3) license to use the Adolor Product Trademarks in the United States during the GI Product Promotion Term to the extent selected by GSK in accordance with Sections 2.4.2 solely in conjunction with the GI Products, and (v) a non-exclusive, non-transferable (except in accordance with Section 2.3) license to use the Adolor Housemark in the ROW solely in conjunction with the Collaboration Products. All rights not expressly granted in the Adolor Housemark and the Adolor Product Trademarks are reserved by Adolor and GSK acknowledges that nothing in this Agreement shall give it any right, title or interest in the Adolor Housemark or the Adolor Product Trademarks other than the

licenses granted herein.

(b) GSK hereby grants to Adolor (i) a non-exclusive, non-transferable (except in accordance with Section 2.3) license to use the GSK Housemark in the United States during the GI Product Promotion Term solely in conjunction with the GI Products, (ii) an exclusive (except as to GSK and its Affiliates), non-transferable (except in accordance with Section 2.3) license to use the GI Product Trademarks in the United States during the GI Product Promotion Term solely in conjunction with the GI Products, (iii) a non-exclusive, non-transferable (except in accordance with Section 2.3) license to use the GSK Housemark in the United States during the Adolor Product Promotion Term solely in conjunction with the Adolor Products, and (iv) an exclusive (except as to GSK and its Affiliates), non-transferable (except in accordance with Section 2.3) license to use the GI Product Trademarks in the United States to the extent selected by Adolor in accordance with Section 2.4.1, subject to Section 16.9.5, solely in conjunction with the Adolor Products. All rights not expressly granted in the GSK Housemark and the GI Product Trademarks are reserved by GSK and Adolor acknowledges that nothing in this Agreement shall give it any right, title or interest in the GSK Housemark or the GI Product Trademarks other than the license granted herein.

(c) The Parties shall use the Adolor Housemark, GSK Housemark, the Adolor Product Trademarks, the GI Product Trademarks and the ROW

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Trademarks with the necessary trademark designations and the Parties shall use Commercially Reasonable Efforts to use the respective Adolor Housemark or GSK Housemark, the Adolor Product Trademarks, the GI Product Trademarks and the ROW Trademarks in a manner that does not derogate from the Parties' rights in the respective trademarks, names and logos and the Parties will take no action that will interfere or diminish the Parties' rights in their respective trademarks, names and logos. The Parties agree that all use of the other's trademarks, names and logos will inure to the benefit of the owner of such trademarks, names and logos.

2.4.5 Marking of Promotional Materials.

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(a) In the United States, to the extent permitted by applicable Laws, the Adolor Housemark and the GSK Housemark shall be given equal exposure and prominence on all Promotional Materials, labeling, package inserts or outserts and packaging for the Adolor Products or samples of Adolor Products during the Adolor Product Promotion Term and GI Products or samples of GI Products during the GI Product Promotion Term.

(b) In the ROW, to the extent permitted by applicable Laws, the Adolor Housemark and the GSK Housemark shall be given equal exposure and prominence on all labeling, package inserts or outserts and packaging for the Collaboration Products or Samples during the ROW Term.

(c) If any Claim for infringement is brought against a Party alleging that its use of the other Party's housemark infringes the intellectual property of a Third Party, the Party with the alleged infringing housemark shall be responsible for defending such claim and for paying all costs associated with such defense and shall indemnify and hold harmless the other Party and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Losses arising out of or relating to such Claim.

#### 2.4.6 Non-Use of Similar Marks. Notwithstanding any other provision

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in this Agreement, during each of the Adolor Product Promotion Term, GI Product Promotion Term or ROW Term, neither Party nor its Affiliates shall market, promote, sell and/or distribute any product (other than the Adolor Product, GI Products or Collaboration Products, as the case may be) under the Adolor Product Trademarks, the GI Product Trademarks or the ROW Trademarks or any substantially similar trade names or trademarks.

#### 2.4.7 Trademark Filings and Expenses. Adolor shall be solely

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responsible for the filing and maintenance of the Adolor Product Trademarks in the United States and all costs and expenses related thereto. GSK shall be solely responsible for the filing and maintenance of (a) the GI Product Trademarks in the United States, and (b) the ROW Trademarks in the ROW, and all costs and expenses related thereto.

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#### 2.4.8 Trademark Infringement.

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(a) Infringement Claims by Third Parties. With respect to any

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and all Claims instituted by Third Parties against Adolor or GSK or any of their  
respective Affiliates for trademark infringement involving the use, sale,  
license or marketing of a Collaboration Product in the United States during the  
United States Term (each, a "Trademark Infringement Claim"), \*\* and Adolor and

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GSK will assist one another and cooperate in the defense and settlement of such  
Trademark Infringement Claims at the other Party's request; provided, however,  
that in all cases referred to in this Section 2.4.8, neither Party shall be  
liable for any proportion of its share of the Losses in relation to the  
Trademark Infringement Claim \*\*.

(b) Infringement of Adolor Product Trademarks. In the event

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that Adolor or GSK becomes aware of actual or threatened infringement of an  
Adolor Product Trademark during the Term, that Party will promptly notify the  
other Party in writing (a "Trademark Infringement Notice"). Adolor will have the

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right but not the obligation to bring an action with respect to such  
infringement against any Third Party for infringement of an Adolor Product  
Trademark. \*\* During the Term, in the event that Adolor does not undertake such  
an infringement action with respect to an Adolor Product Trademark, upon  
Adolor's written consent, which shall not be unreasonably withheld, refused,  
conditioned or delayed, GSK shall be

\*\* = Certain information on this page has been omitted and filed separately with  
the Commission. Confidential treatment has been requested with respect to the  
omitted portions.

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permitted to do so. If Adolor has consented to an infringement action but GSK is  
not recognized by the applicable court or other relevant body as having the



requisite standing to pursue such action, then GSK may join Adolor as party-plaintiff. \*\*.

(c) Infringement of GI Product Trademarks. In the event that

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GSK or Adolor becomes aware of actual or threatened infringement of a GI Product Trademark during the Term, that Party will promptly notify the other Party in writing. GSK will have the right but not the obligation to bring an action with respect to such infringement against any Third Party for infringement of a GI Product Trademark. \*\*. During the Term, in the event that GSK does not undertake such an infringement action with respect to a GI Product Trademark, upon GSK's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, Adolor shall be permitted to do so. If GSK has consented to an infringement action but Adolor is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then GSK may be joined as a party-plaintiff. \*\*

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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(d) Infringement of ROW Trademarks.

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(i) In the event that GSK or Adolor becomes aware of actual or threatened infringement of a ROW Trademark during the ROW Term, that Party will promptly notify the other Party in writing.

(ii) \*\*.

(iii) \*\*. During the Term, in the event that GSK does not undertake such an infringement action \*\*, upon GSK's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, Adolor shall be permitted to do so. If GSK has consented to an infringement action but Adolor is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then GSK may be joined as a party-plaintiff. If Adolor elects to pursue such infringement action, GSK may \*\*

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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\*\*

(e) Infringement of Adolor Housemark or GSK Housemark. In the

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event that GSK or Adolor becomes aware of actual or threatened infringement of the other Party's housemark during the Term, that Party will promptly notify the other Party in writing. Each Party will have the right but not the obligation to bring an infringement action against any Third Party in relation to such infringement of their respective housemark. \*\*

#### 2.5 Intellectual Property.

##### 2.5.1 No Other GSK Rights. Except for the express rights granted to

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GSK in this Agreement, GSK shall not enjoy or exercise any proprietary or property right or otherwise have any other right, title or interest in the Adolor Product Trademarks, the Adolor Housemark, the Adolor Inventions, the Adolor Patents, the Adolor Know-How or in any copyright owned by Adolor or any of its Affiliates, and GSK shall not represent to any Third Party that it has any such proprietary or property right, or any other right, title or interest.

##### 2.5.2 No Other Adolor Rights. Except for the express rights granted

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to Adolor in this Agreement, Adolor shall not enjoy or exercise any proprietary or property right or otherwise have any other right, title or interest in the GSK Housemark, the GI Product Trademarks, the ROW Trademarks, the GSK Inventions, the GSK Patents, the GSK Know-How or in any copyright owned by GSK or any of its Affiliates, and Adolor shall not represent to any Third Party that it has any such proprietary or property right, or any other right, title or interest.

##### 2.5.3 Ownership of Inventions. Each Party shall promptly disclose to

the other Party all Inventions made by it during the Term. Adolor shall own all Adolor Inventions and GSK shall own all GSK Inventions. All Joint Inventions shall be owned jointly by Adolor and GSK, and each Party hereby consents to the assignment or license or other disposition by the other Party of its joint interests in Joint Inventions without the need to seek the consent of the other Party to such assignment or license or other disposition; provided that any such assignment, license or other disposition shall at all times be subject to the grant of rights under Sections 2.1 and 2.2. The determination of inventorship for Inventions shall be made in accordance with applicable laws relating to inventorship set forth in the patent laws of the United States (Title 35, United States Code).

## 2.6 \*\*

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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2.7 OTC Rights. During the United States Term or ROW Term, as the case

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may be, on a Collaboration Product-by-Collaboration Product basis, Adolor will not seek to switch a Collaboration Product from prescription status to OTC status without the prior written consent of GSK. If Adolor intends to directly or indirectly sell or offer for sale in collaboration with a Third Party (a) any Collaboration Product as an OTC product in the United States within \*\* (\*\*) years following expiration of the United States Term or (b) any Collaboration Product in the ROW within \*\* (\*\*) years following expiration of the ROW Term, then at least \*\* (\*\*) days prior to taking substantial steps toward developing such Collaboration Product as an OTC Product, Adolor shall give GSK notice of such intention, and for the \*\* (\*\*) day period following delivery of such notice, the Parties shall negotiate exclusively with each other commercial terms under which Adolor and GSK would Commercialize such Collaboration Product as an OTC Product. Neither Party shall be obligated to agree upon any such terms or to accept any terms proposed by the other Party.

ARTICLE 3

GOVERNANCE OF DEVELOPMENT AND

COMMERCIALIZATION OF PRODUCTS

3.1 Joint Steering Committee.

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3.1.1 Members; Officers. Within thirty (30) days after the Effective

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Date, the Parties shall establish a joint steering committee (the "Joint

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Steering Committee"), which shall consist of six (6) members, three (3) of whom

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shall be designated by each of GSK and Adolor and shall have appropriate expertise, with at least two (2) members from each Party being at least at a vice president level. Each of GSK and Adolor may replace any or all of its representatives on the Joint Steering Committee at any time upon written notice to the other Party. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at any meeting of the Joint Steering Committee. GSK and Adolor each may, on advance written notice to the other Party, invite non-member representatives of such Party to attend meetings of the Joint Steering Committee. The Joint Steering Committee shall be chaired on an annual rotating basis by a representative of either Adolor or GSK, as applicable, on the Joint Steering Committee, with Adolor providing the first such chairperson. The chairperson shall appoint a secretary of the Joint Steering Committee, who shall be a

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representative of the other Party and who shall serve for the same annual term as such chairperson.

3.1.2 Responsibilities. The Joint Steering Committee shall

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perform the following functions:

(a) Manage and oversee the Development and

Commercialization of the Collaboration Products in the United States pursuant to the terms of this Agreement;

(b) Review and approve the U.S. Development Plans and the

U.S. Marketing Plans for Collaboration Products and any material amendments to the U.S. Development Plans and U.S. Marketing Plans;

(c) Coordinate Development and Commercialization of the

Collaboration Products in the ROW with the Development and Commercialization of the Collaboration Products in the United States with appropriate liaison with the Joint Development Committee and the Joint Marketing Committee;

(d) At each meeting of the Joint Steering Committee,

review a comparison of actual Development Expenses and Marketing Expenses for the United States to the budgeted Development Expenses and Marketing Expenses for the United States for the year-to-date, as current as practicable to a date immediately prior to the date of the meeting;

(e) Review and approve the progress of the other committees;

(f) Review and approve the trademarks selected under Section 2.4;

(g) Review and approve "go/no-go" decisions and other matters referred to the Joint Steering Committee, including, without limitation, the continued Development of a particular Collaboration Product or the inclusion of Additional Products;

(h) Life cycle management of, and intellectual property protection for, the Collaboration Products in the United States;

(i) Approve any and all \*\* policies and \*\* in the \*\* for Collaboration Products, including \*\*;

(j) In accordance with the procedures established in Section 3.1.4, resolve disputes, disagreements and deadlocks unresolved by the other committees; and

(k) Have such other responsibilities as may be assigned to the Joint Steering Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

\*\* = Certain information on this page has been omitted and filed separately with

the Commission. Confidential treatment has been requested with respect to the omitted portions.

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3.1.3 Meetings. The Joint Steering Committee shall meet in

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person at least three (3) times during every Calendar Year, and more frequently as GSK and Adolor deem appropriate or as required to resolve disputes, disagreements or deadlocks in the other committees, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the Joint Steering Committee within thirty (30) days after the establishment of the Joint Steering Committee. The Joint Steering Committee shall arrange to meet in person or convene otherwise to assess and approve any U.S. Development Plans or U.S. Marketing Plans, if any, submitted to the Joint Steering Committee in each Calendar Year so that such plans will be reviewed and approved within thirty (30) days following submission to the Joint Steering Committee. To the extent any such U.S. Development Plans or U.S. Marketing Plans are not approved and need to be reformulated by the Joint Development Committee or Joint Marketing Committee, such plans shall be reviewed by the Joint Steering Committee as soon as reasonably practicable after resubmission of same. Meetings of the Joint Steering Committee that are held in person shall alternate between offices of GSK and Adolor, or such other place as such Parties may agree. The members of the Joint Steering Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

3.1.4 Decision-Making.

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(a) The Joint Steering Committee may make decisions with respect to any subject matter that is subject to the Joint Steering Committee's decision-making authority and functions as set forth in Section 3.1.2. Except as specified in Section 3.1.4(b), all decisions of the Joint Steering Committee shall be made by unanimous vote or written consent, with GSK and Adolor each having, collectively, among its respective members, one vote in all decisions.

The Joint Steering Committee shall use \*\* to resolve the matters within its roles and functions or otherwise referred to it.

(b) With respect to any issue, if the Joint Steering Committee cannot reach consensus within ten (10) Business Days after the matter has been brought to the Joint Steering Committee's attention, then such issue shall be referred to the Chief Executive Officer of Adolor and the Chairman R&D of GSK for Development issues and the Chief Executive Officer of Adolor and the President (U.S.) of GSK for Commercialization issues (the "Officers") for

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resolution.\*\*

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(c) Notwithstanding any other provision of this Agreement to the contrary, the decision to \*\* shall require the unanimous consent of the Joint Steering Committee, and such issue shall not be subject to the dispute resolution provision of Sections 18.5.2 and 18.5.3.

### 3.2 Joint Development Committee.

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3.2.1 Members; Officers. Within thirty (30) days after

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the Effective Date, the Parties shall establish a Development Committee (the "Joint Development Committee"), and GSK and Adolor shall designate an equal

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number of representatives, up to a maximum total of eight (8) members on such Joint Development Committee. Each of GSK and Adolor may replace any or all of its representatives on the Joint Development Committee at any time upon written notice to the other Party. Such representatives shall include individuals who have clinical trial and regulatory experience and expertise in pharmaceutical drug development. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at any meeting of the Joint

Development Committee. GSK and Adolor each may, on advance written notice to the other Party, invite non-member representatives of such Party to attend meetings of the Joint Development Committee. The Joint Development Committee shall be chaired on an annual rotating basis by a representative of either Adolor or GSK, as applicable, with Adolor providing the first such chairperson. The chairperson shall appoint a secretary of the Joint Development Committee, who shall be a representative of the other Party and who shall serve for the same annual term as such chairperson.

### 3.2.2 Responsibilities. The Joint Development Committee

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shall perform the following functions:

- (a) Manage and oversee the preparation and implementation of the U.S. Development Plans;
- (b) As early as necessary in each year beginning with the first full Calendar Year after the Effective Date, update and amend the initial U.S. Development Plans and prepare the U.S. Development Plans for each Collaboration Product for the following Calendar Year so that it can submit such proposed U.S. Development Plans to the Joint Steering Committee no later than \*\* of such year for review and approval;

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- (c) Prepare the Development strategy and develop protocols for clinical studies for the Collaboration Products for Commercialization in the United States;
- (d) Review and recommend to the Joint Steering Committee any material amendments or modifications to the U.S. Development Plans;
- (e) Coordinate and monitor regulatory strategy and activities for the Collaboration Products in accordance with Article 9;
- (f) At each meeting of the Joint Development Committee, review a comparison of actual Development Expenses for the United



States to the budgeted Development Expenses for the United States in the U.S.

Development Plan for the year-to-date, as current as practicable to a date

immediately prior to the date of the meeting;

(g) Review and recommend to the Joint Steering

Committee "go/no-go" decisions for the Development of Collaboration Products in

the United States; and

(h) Have such other responsibilities as may be

assigned to the Joint Development Committee pursuant to this Agreement or as may

be mutually agreed upon by the Parties from time to time.

3.2.3 Meetings. The Joint Development Committee shall meet in

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person at least once during every Calendar Quarter, and more frequently as GSK

and Adolor deem appropriate or as reasonably requested by either such Party, on

such dates, and at such places and times, as such Parties shall agree; provided

that the Parties shall endeavor to have the first meeting of the Joint

Development Committee within thirty (30) days after the establishment of the

Joint Development Committee. Meetings of the Joint Development Committee that

are held in person shall alternate between the offices of GSK and Adolor, or

such other place as the Parties may agree. The members of the Joint Development

Committee also may convene or be polled or consulted from time to time by means

of telecommunications, video conferences, electronic mail or correspondence, as

deemed necessary or appropriate.

3.2.4 Development Budget. The Joint Development Committee shall

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review on a quarterly basis the actual Development Expenses against the budget

for such expenses in the applicable Calendar Year. If in the course of its

quarterly review of Development Expenses, the Joint Development Committee should

determine for any Collaboration Product that for any study or activity the

actual amounts incurred are likely to be higher than budgeted, the Joint

Development Committee shall review the reasons for such potential overrun and

determine whether such overrun is appropriate. If the Joint Development

Committee determines that such overrun is appropriate, the Joint Development

Committee will assess whether such overrun is likely to result in an overrun of

the budget for Development

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Expenses for such Collaboration Product and if required, will agree on a revised budget for such Development Expenses for such Collaboration Product for subsequent approval by the Joint Steering Committee. If the Joint Development Committee determines that such overrun is not appropriate, the Joint Development Committee will take such actions as required to remedy the situation.

3.2.5 Decision-Making. The Joint Development Committee may make

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decisions with respect to any subject matter that is subject to the Joint Development Committee's decision-making authority and functions as set forth in Section 3.2.2. All decisions of the Joint Development Committee shall be made by unanimous vote or written consent, with GSK and Adolor each having collectively, among its respective members, one vote in all decisions. If the Joint Development Committee cannot reach consensus within \*\* (\*\*) Business Days after it has first met and attempted to reach such consensus, the matter shall be referred on the \*\* (\*\*) Business Day to the Joint Steering Committee for resolution.

3.3 Joint Marketing Committee.

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3.3.1 Members; Officers. Within thirty (30) days after the

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Effective Date, the Parties shall establish a commercialization committee (the "Joint Marketing Committee"), and GSK and Adolor shall designate an equal number

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of representatives, up to a maximum total of eight (8) members on the Joint Marketing Committee. Each of GSK and Adolor may replace any or all of its representatives on the Joint Marketing Committee at any time upon written notice to the other. Such representatives shall include individuals who have experience and expertise in pharmaceutical product marketing, sales and regulatory matters. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at any meeting of the Joint Marketing Committee. GSK and Adolor each may, upon prior written notice to the other Party, invite non-member representatives of such Party to attend meetings of the

Joint Marketing Committee. The Joint Marketing Committee shall be chaired on an annual rotating basis by a representative of either Adolor or GSK, as applicable with GSK providing the first such chairperson. The chairperson shall appoint a secretary of the Joint Marketing Committee, who shall be a representative of the other Party and who shall serve for the same annual term as such chairperson.

3.3.2 Responsibilities. The Joint Marketing Committee shall

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perform the following functions:

- (a) Manage and oversee the preparation and implementation of the U.S. Marketing Plans;
- (b) Review and recommend to the Joint Steering Committee any material amendments or modifications to the U.S. Marketing Plans, including those pursuant to Section 5.1.6;

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- (c) Coordinate and monitor regulatory strategy and activities for Phase IV Studies in support of Collaboration Products that are Commercialized in the United States in accordance with Article 9;
- (d) Make any changes to the Target Audience; provided, however, the Parties shall not be required to implement such changes within one hundred eighty (180) days of such change;
- (e) Discuss the state of the markets for Collaboration Products in the United States and opportunities and issues concerning the Commercialization of the Collaboration Products in the United States, including consideration of marketing and promotional strategy, marketing research plans, labeling, Collaboration Product positioning and Collaboration Product profile issues, to determine the kind of marketing and selling efforts that are appropriate, in accordance with the U.S. Marketing Plans;
- (f) Review data and reports arising from and generated in connection with the Commercialization of the Collaboration Products in the United States, including, but not limited to the U.S. Marketing Plans, marketing

budgets and sales forecasts;

(g) At each meeting of the Joint Marketing Committee, review a comparison of actual sales and Marketing Expenses in the United States to the budgeted Sales and Marketing Expenses in the relevant U.S. Marketing Plan for the year-to-date, as current as practicable to a date immediately prior to the date of the meeting;

(h) Review and approve the general guidelines applicable to particular Collaboration Products to be followed for Promotional Materials to be used by Adolor and GSK in the promotion of such Collaboration Products (such guidelines to be consistent with then current U.S. Marketing Plan applicable to such Collaboration Products); and

(i) Have such other responsibilities as may be assigned to the Joint Marketing Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

3.3.3 Meetings. The Joint Marketing Committee shall meet in person

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at least once during every Calendar Quarter, and more frequently as GSK and Adolor deem appropriate or as reasonably requested by either such Party, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the Joint Marketing Committee within thirty (30) days after the establishment of the Joint Marketing Committee. Meetings of the Joint Marketing Committee that are held in person shall alternate between the offices of GSK and Adolor, or such other place as such Parties may agree. The members of the Joint Marketing Committee also may convene or be polled or

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consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

3.3.4 Marketing Budget. The Joint Marketing Committee shall review

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on a quarterly basis the actual Marketing Expenses against the budget for such expenses in the applicable Calendar Year. If in the course of its quarterly review of Marketing Expenses, the Joint Marketing Committee should determine for

any Collaboration Product that for any study or activity the actual amounts incurred are likely to be higher than budgeted, the Joint Marketing Committee shall review the reasons for such potential overrun and determine whether such overrun is appropriate. If the Joint Marketing Committee determines that such overrun is appropriate, the Joint Marketing Committee will assess whether such overrun is likely to result in an overrun of the budget for Marketing Expenses for such Collaboration Product on an annual basis and if required, will agree on a revised budget for such Marketing Expenses for such Collaboration Product for subsequent approval by the Joint Steering Committee. If the Joint Marketing Committee determines that such overrun is not appropriate, the Joint Marketing Committee will take such actions as required to remedy the situation.

3.3.5 Decision-Making. The Joint Marketing Committee may make

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decisions with respect to any subject matter that is subject to the Joint Marketing Committee's decision-making authority and functions as set forth in Section 3.3.2. All decisions of the Joint Marketing Committee shall be made by unanimous vote or written consent, with GSK and Adolor each having collectively, among its respective members, one vote in all decisions. If the Joint Marketing Committee cannot reach consensus within \*\* (\*\*\*) Business Days after it has first met and attempted to reach such consensus, the matter shall be referred on the \*\* (\*\*\*) Business Day to the Joint Steering Committee for resolution.

3.4 Joint Supply Committee.

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3.4.1 Members; Officers. Within thirty (30) days after the Effective

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Date, the Parties shall establish a supply committee (the "Joint Supply

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Committee"), and GSK and Adolor shall designate an equal number of

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representatives, up to a maximum total of eight (8) members on such Joint Supply Committee. Each of GSK and Adolor may replace any or all of its representatives on the Joint Supply Committee at any time upon written notice to the other Party. Such representatives shall include individuals who have supply chain management experience. A Party may designate a substitute to temporarily attend

and perform the functions of such Party's designee at any meeting of the Joint Supply Committee. GSK and Adolor each may, on advance written notice to the other Party, invite non-member representatives of such Party to attend meetings of the Joint Supply Committee. The Joint Supply Committee shall be chaired on an annual rotating basis by a representative of either Adolor or GSK, as applicable, with GSK providing the first such chairperson. The chairperson shall appoint a secretary of the Joint Supply Committee, who shall be a representative of the other Party and who shall serve for the same annual term as such chairperson.

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3.4.2 Responsibilities. The Joint Supply Committee shall perform

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the following functions:

(a) Manage and oversee the activities in relation to manufacture and supply of API Compound and Collaboration Products for use in Development and Commercialization and establish procedures and protocols for testing API Compound and Collaboration Products to ensure that such API Compound and Collaboration Products comply with the specifications (the "Testing

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Protocol"). The Parties will utilize such Testing Protocol with respect to API

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Compound and Collaboration Product that they may receive from Product Suppliers to ensure that such API Compound or Collaboration Product meets specifications;

(b) Recommend and coordinate necessary adjustments to the manufacturing schedule to ensure it is meeting the needs for all Collaboration Products;

(c) Coordinate allocation of API Compound in the event of a shortage between the United States and the ROW, it being understood that, in the event of \*\*;

(d) Review the quality of the manufacture of the

Collaboration Products, reviewing as appropriate reports of the manufacturers of API Compound and Collaboration Products and reports as to the quality of any packaging that bears the relevant trademarks or housemarks of the Parties (as owned by or licensed to the relevant Party under Section 2.4) as prescribed by this Agreement;

(e) Recommend and implement optimal inventory levels and safety stock targets;

(f) Set improvement targets and monitor performance against these targets for cost, yield, delivery and other appropriate measures;

(g) Establish guidelines to facilitate improved efficiencies and compliance with current Good Manufacturing Practices by Product Suppliers; and

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(h) Have such other responsibilities as may be assigned to the Joint Supply Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

3.4.3 Meetings. The Joint Supply Committee shall meet in person at

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least once during every Calendar Quarter, and more frequently as GSK and Adolor deem appropriate or as reasonably requested by either such Party, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the Joint Supply Committee within thirty (30) days after the establishment of the Joint Supply Committee. Meetings of the Joint Supply Committee that are held in person shall alternate between the offices of GSK and Adolor, or such other place as the Parties may agree. The members of the Joint Supply Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

3.4.4 Decision-Making. The Joint Supply Committee may make

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decisions with respect to any subject matter that is subject to the Joint Supply Committee's decision-making authority and functions as set forth in Section

3.4.2. All decisions of the Joint Supply Committee shall be made by unanimous vote or written consent, with GSK and Adolor each having collectively, among its respective members, one vote in all decisions. If the Joint Supply Committee cannot reach consensus within \*\* (\*\*) Business Days after it has first met and attempted to reach such consensus, the matter shall be referred on the \*\* (\*\*) Business Day to the Joint Steering Committee for resolution. Notwithstanding the foregoing, any matter relating to supply of API Compound or any Collaboration Product assigned for decision-making to a Party in Article 10 or in the further agreements between the Parties contemplated thereby shall not be subject to referral to the Joint Steering Committee.

3.5 Minutes of Committee Meetings. Definitive minutes of all committee

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meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain as follows:

3.5.1 Distribution of Minutes. Within ten (10) days after a

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committee meeting, the secretary of such committee shall prepare and distribute to all members of such committee draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within such committee or through the relevant resolution process.

3.5.2 Review of Minutes. The Party members of each committee shall

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have ten (10) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of such committee.

3.5.3 Discussion of Comments. Upon the expiration of such second ten

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(10) day period, the Parties shall have an additional ten (10) days to discuss each other's comments and finalize the minutes. The secretary and chairperson(s) of such

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omitted portions.

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committee shall each sign and date the final minutes. The signature of such chairperson(s) and secretary upon the final minutes shall indicate each Party's assent to the minutes.

3.6 Expenses. Each Party shall be responsible for all travel and related

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costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, a committee.

3.7 Initial Coordination Efforts. The Parties intend, following the

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Effective Date, to organize meetings of internal staff to communicate and explain the provisions of this Agreement to ensure the efficient and timely Development and Commercialization of the Collaboration Products.

#### ARTICLE 4

##### DEVELOPMENT OF PRODUCTS

4.1 Responsibilities of the Parties. Subject to the general oversight of

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the Joint Development Committee, and subject in all instances to the specific provisions relating to regulatory matters referred to in Article 9:

4.1.1 Adolor Products. Adolor shall have the overall responsibility

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for the performance of all Development activities, including regulatory filings, for each Adolor Product that is required to obtain Marketing Authorization for the Adolor Products in the United States and, in furtherance thereof, the Parties shall perform the Development activities, all in accordance with the applicable U.S. Development Plan, for an Adolor Product. The Parties acknowledge that Adolor is in the process of conducting clinical studies on the POI Product necessary to file the NDA.

4.1.2 OBD Chronic Product. GSK shall have the overall responsibility

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for the performance of all Development activities, including regulatory filings, of the OBD Chronic Product that is required to obtain Marketing Authorization

for the OBD Chronic Product in the United States and, in furtherance thereof, the Parties shall perform Development activities, all in accordance with the applicable U.S. Development Plan, for the OBD Chronic Product. The Parties acknowledge that Adolor is in the process of conducting clinical studies on the OBD Chronic Product necessary to file the NDA and such activities \*\*. To the extent such transfer is not timely made, the time period of any delay in transfer shall toll the timeline for Development of the OBD Chronic Product as set forth in the applicable U.S. Development Plan.

4.1.3 Other GI Products. GSK shall be solely responsible for the

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performance of all Development activities, including regulatory filings, for each GI Product (other than the OBD Chronic Product covered in Section 4.1.2) that is required to obtain Marketing Authorization in the United States for such GI Products in accordance with the applicable U.S. Development Plan for such GI Products.

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4.2 Obligations for Development.

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4.2.1 General. The Parties shall use \*\* to Develop the Collaboration

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Products for Commercialization.

4.2.2 GSK's Obligations. In furtherance of the foregoing, and

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subject to GSK's termination rights pursuant to Article 16 (including those safety related termination rights pursuant to Section 16.4), \*\*.

4.3 Additional Products. At any time after the Effective Date, either

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Party may make a written proposal to the Joint Development Committee regarding the Development of an Additional Product. Such proposal shall include (i) any data and other information in its possession which may be relevant to the use of

the proposed Product, (ii) a reasonably detailed outline of the major Development activities required to obtain Marketing Authorization for such proposed Product in the United States, including a timeline for performing such activities, (iii) an estimated budget for the expected Development Expenses and Marketing Expenses for such proposed Product, (iv) an appropriate market analysis of the proposed Product (including market size, competitive analysis, etc.), and (v) preliminary sales forecasts and estimated Cost of Goods for the proposed Product. Thereafter, the Joint Development Committee shall meet in order to review such proposal.

#### 4.3.1 Inclusion of Additional Products. With respect to a proposal

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pursuant to Section 4.3, if the Joint Development Committee accepts, or if the Joint Development Committee cannot agree and the Joint Steering Committee unanimously accepts, such proposal, such proposed Product shall be an Additional Product, and the Joint Development Committee shall prepare a U.S. Development Plan for such Additional Product. The Joint Development Committee shall also at the same time designate such Additional Product as either an Adolor Product or a GI Product, it being understood that the \*\* Product and any other Additional Product that is to be primarily promoted to or used by health care providers in  
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hospitals shall be designated an Adolor Product, unless otherwise mutually agreed by the Parties. In the event of disagreement between the Parties regarding the inclusion of an Additional Product within the Joint Development Committee such that the matter is referred to the Joint Steering Committee, the Joint Steering Committee must agree unanimously upon its inclusion even if such proposed Additional Product has already been designated by the Joint Development Committee as an Adolor Product or a GI Product as contemplated under this Section 4.3.1 and, therefore, the provisions of Section 3.1.4(b) shall not apply.

#### 4.3.2 Disagreement Regarding Additional Product. If the Joint

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Development Committee or the Joint Steering Committee, as the case may be, does not accept such proposal (unanimously in the case of the Joint Steering Committee), such proposed Additional Product shall not become a Collaboration Product; provided, however, if GSK proposes an Additional Product and Adolor does not desire to Develop or Commercialize such proposed Additional Product in the United States, GSK may Develop and Commercialize such proposed Additional Product in the ROW subject to Section 4.3.3.

#### 4.3.3 Independent Development and Commercialization of

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Additional Products in the ROW.  
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(a) If GSK desires to Develop and Commercialize a proposed Additional Product in the ROW pursuant to Section 4.3.2, GSK may do so, provided that:

(i) the Development or Commercialization of such Additional Product in \*\* does not \*\* on \*\* being Developed or Commercialized in \*\*, and

(ii) GSK takes into account the goal of optimizing the best overall commercial potential of the Collaboration Products.

(b) Subject to this Section 4.3.3, if GSK elects to Develop or Commercialize such proposed Additional Products in the ROW, then (i) such proposed Additional Products shall be referred to herein as a "GSK Other GI

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Product", (ii) GSK shall be solely responsible for all costs and expenses

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related to the Development and Commercialization in the ROW of such GSK Other GI Product, and (iii) all provisions of this Agreement relating to Collaboration Products in the ROW shall apply to such GSK Other GI Product.

(c) Notwithstanding anything in the foregoing to the contrary, the Development and Commercialization of the GSK Other GI Product in the ROW shall be subject to the oversight of the Joint Development Committee, Joint Marketing Committee and the Joint Steering Committee in accordance with Sections 3.1.2(c).

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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#### 4.4 U.S. Development Plans.

##### 4.4.1 Initial U.S. Development Plan for POI Product. The

initial U.S. Development Plan for all Development activities for the POI Product, which the Parties hereby approve, is attached to this Agreement as Schedule 1.146.

##### 4.4.2 Initial U.S. Development Plan for OBD Chronic Product.

The initial U.S. Development Plan for all Development activities for the OBD Chronic Product, which the Parties hereby approve, is attached to this Agreement as Schedule 1.146. In the United States, the average total daily dose of

Compound in an OBD Chronic Product recommended in the FDA approved label shall be not more than one (1) milligram.

##### 4.4.3 U.S. Development Plans for the \*\* Product and

\*\* Product. \*\*. In the United States, the total daily dose of Compound (in milligrams) in either the \*\* Product or the \*\* Product shall be less than \*\* percent (\*\*%) of the average total daily dose of Compound (in milligrams) recommended in the FDA approved label in the POI Product. In the event that a Collaboration Product other than the POI Product receives the first Marketing Authorization Approval in the United States, then such percentage limitation on dose of Compound shall be redefined by the Parties.

##### 4.4.4 U.S. Development Plan for OBD Acute Product. The

Parties acknowledge that Adolor is \*\* in connection with the Development of the

POI Product and the cost of such study will be included as a Development Expense for the purposes of Section 4.6.2. \*\*. If Adolor desires to proceed with the Development of the OBD Acute Product and such Development will not or is not likely to \*\*, Adolor shall so notify the Joint Development Committee (of its desire to proceed with Development of the OBD Acute Product and the reasons why such Development will not significantly or adversely affect the commercial viability of the POI Product), and thereafter, in accordance with Section 4.4.5, the Parties shall proceed with the Development of the OBD Acute Product subject to Section 4.6.1. In the United States, the total daily dose of Compound (in milligrams) in the OBD Acute Product shall not be less than \*\* percent (\*\*%) of the average total daily dose of Compound (in milligrams) recommended in the FDA approved label in the POI Product. In the event that a Collaboration Product other than the POI Product receives the first Marketing Authorization Approval in the United States, then such percentage limitation on dose of Compound shall be redefined by the Parties.

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#### 4.4.5 U.S. Development Plans for Additional Products. When an

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Additional Product is added as a Collaboration Product pursuant to Section 4.3, within sixty (60) days following the date of such inclusion, for those Additional Products designated Adolor Products, Adolor shall prepare, and for those Additional Products designated GI Products, GSK shall prepare, for review by the Joint Development Committee and approval by the Joint Steering Committee, a U.S. Development Plan for each such Additional Product.

#### 4.4.6 Updates to the U.S. Development Plans. As early as

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necessary in each year beginning with the first full Calendar Year after the Effective Date, the Joint Development Committee shall update and amend the initial U.S. Development Plans and prepare the U.S. Development Plans for each Collaboration Product for the following Calendar Year so that it can submit such

proposed U.S. Development Plans to the Joint Steering Committee no later than

\*\* of such year for review and approval.

#### 4.4.7 Criteria for U.S. Development Plans. The U.S.

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Development Plan for each Collaboration Product shall contain at a minimum a list and description of preclinical and clinical activities, timelines for the performance of studies in support of the Development activities for such Collaboration Product and a budget for the Development Expenses to complete such Development activities.

#### 4.5 Implementation of U.S. Development Plans. Each Party will

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inform the Joint Development Committee of ongoing implementation of the U.S. Development Plan and consider timely recommendations for improving the U.S. Development Plan. In connection with the preparation and implementation of the U.S. Development Plan, Adolor and GSK will make available to the Joint Development Committee any information then in their possession pertaining to the Collaboration Products useful for such Development activities.

#### 4.6 Development Funding.

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##### 4.6.1 Development Budgets. The Development budgets for each

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Collaboration Product to be Commercialized in the United States shall be set forth in the U.S. Development Plan for such Collaboration Product. Such Development budget shall be sufficient to fund all necessary studies and related activities necessary to obtain Marketing Authorization Approval for such Collaboration Product. Notwithstanding the foregoing, unless otherwise agreed to by the Parties, the total Development budget for an Adolor Product, the OBD Chronic Product or for any other GI Product for which Adolor elects to fund Development Expenses pursuant to Section 4.6.5, shall not \*\* percent (\*\*%) of the budget set forth in the most recently approved U.S. Development Plan for such Collaboration Product. The budgets for the POI Product and the OBD Chronic Product are set forth in the applicable U.S. Development Plan attached hereto as Schedule 1.146. Subject to the percentage increase provisions of this Section

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4.6.1, the initial Development budget for the OBD Acute Product shall not exceed

\*\* United States Dollars (US\$\*\*).

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4.6.2 Adolor Products in the United States. Subject to

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reconciliation as provided in Section 6.7.5, Adolor shall be responsible and pay for \*\* percent (\*\*%) and GSK shall be responsible and pay for \*\* percent (\*\*%) of the Development Expenses for each Adolor Product for Commercialization in the United States incurred from January 1, 2002 through the First Commercial Sale for such Adolor Product. Thereafter, Development Expenses, if any, for each Adolor Product shall be shared in accordance with \*\*. With respect to the OBD Acute Product, Adolor shall be solely responsible for (and such expenses shall not be deemed Development Expenses) expenses related to the Development of the OBD Acute Product incurred prior to the determination to proceed with the Development of the OBD Acute Product in accordance with Section 4.4.4 other than those expenses associated with clinical study 14CL306 which are set forth in Schedule 1.146.

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4.6.3 OBD Chronic Product and Other GI Products in the United

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States. Subject to reconciliation as provided in Section 6.7.5, Adolor shall be

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responsible and pay for \*\* percent (\*\*%) and GSK shall be responsible and pay for \*\* percent (\*\*%) of the Development Expenses in connection with the Development of the OBD Chronic Product for Commercialization in the United States incurred from January 1, 2002 through the First Commercial Sale for such OBD Chronic Product as set forth in the U.S. Development Plan for the OBD Chronic Product attached hereto as Schedule 1.146. Thereafter, Development

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Expenses, if any, for the OBD Chronic Product shall be shared in accordance with



\*\* Subject to Section 4.6.5, GSK shall have sole responsibility to pay for all

Development Expenses incurred in connection with the Development of any and all other GI Products.

#### 4.6.4 Payment of Expenses; Development Expense Account.

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Unless otherwise agreed to by the Joint Development Committee, all Development Expenses for the POI Product for Commercialization in the United States shall be incurred by Adolor, subject to reimbursement as provided for herein. Subject to each Party's relative percentage to fund Development Expenses set forth in this Section 4.6 and reconciliation as provided in Section 6.7.5 and as set forth in the preceding sentence, each Party shall be responsible to pay for all Development Expenses incurred in performing its obligations in connection with any Development activities under a U.S. Development Plan. Each Party shall charge all such expenses so incurred to a separate account created by it on its books and records solely for the purpose of tracking Development Expenses, identifying all Development Expenses by Collaboration Product being Developed.

#### 4.6.5 Election to Fund GI Products in the United States.

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(a) Notwithstanding Section 4.6.3, at Adolor's sole and absolute discretion, Adolor may elect to fund \*\* percent (\*\*%) of the Development Expenses of any GI Product in the United States (other than the OBD  
  
\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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Chronic Product, which is set forth in Section 4.6.3) incurred from the commencement of any \*\* Study for such GI Product (it being understood that the studies and activities for such GI Product of the type set forth on Schedule

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4.6.5A shall be included in the Development Expenses at \*\* percent (\*\*%) of the

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cost thereof in recognition of the applicability of such studies or activities in the ROW as well as in the United States). As soon as practicable after

completion of all \*\* Studies, and a decision by GSK to proceed to a \*\* Study for a GI Product, GSK shall provide Adolor for its review results of all such \*\* Studies and any updates to the most recent U.S. Development Plan, proposed \*\* Study protocols and a proposed U.S. Marketing Plan for such GI Product. Such proposed U.S. Marketing Plan shall be subject to the procedures set forth in Schedule 4.6.5B. Adolor's election to fund such Development Expenses of a GI

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Product (which shall be made on a GI Product-by-GI Product basis) shall be made by Adolor providing written notice to GSK of its election to fund Development Expenses no more than thirty (30) Business Days after Adolor's receipt of all such information. Adolor's obligations to fund such Development Expenses for any GI Product pursuant to this Section 4.6.5 shall continue from the date of such written notice unless and until Adolor makes a Royalty Conversion Election for such GI Product as provided in Section 6.3.5. In the event that the dosage form and strength for the \*\* Product and the \*\* Product are the same, then Adolor shall make the same election with respect to funding Development Expenses in the United States or making a Royalty Conversion Election for both the \*\* Product and the \*\* Product.

(b) In the event that Adolor has elected not to fund \*\* percent (\*\*%) of such Development Expenses of a GI Product, then, within ninety (90) days following the NDA Acceptance date with respect to such GI Product, GSK shall provide to Adolor a report of the actual Development Expenses for such GI Product through the conclusion of \*\* Studies. In the event that such actual Development Expenses are less than \*\* percent (\*\*%) of the proposed budget as set forth in the information submitted by GSK under subsection (a) above, Adolor shall have thirty (30) days after receipt of such report to elect to pay GSK an amount equal to \*\* percent (\*\*%) of the actual Development Expenses incurred from the commencement of any \*\* Study for such GI Product and thereby share in the GI Product Marketing Contribution for such GI Product in accordance with Section 6.3.2 and subject to Adolor's right to make a Royalty Conversion Election for such GI Product.

#### 4.7 Development in the ROW.

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4.7.1 GSK Responsibility. GSK shall have sole responsibility

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for Developing Collaboration Products for Commercialization in the ROW. GSK shall bear all

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costs and expenses associated with the Development of Products for Commercialization in the ROW.

#### 4.7.2 ROW Development Plan; Coordination; Semi-Annual

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Reports. As early as necessary in each year beginning with the first full

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Calendar Year after the Effective Date, GSK shall prepare a Development plan for each Collaboration Product in the ROW (each, a "ROW Development Plan") so that

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it can submit such ROW Development Plans to the Joint Steering Committee no later than September 30 of such year for review. GSK shall coordinate its Development activities for Collaboration Products in the ROW with the Joint Development Committee and provide the Joint Development Committee semi-annual reports within thirty (30) days after June 30 and December 31 of each Calendar Year. Such reports shall set forth in summary form the results of GSK's Development activities with respect to Collaboration Products for Commercialization in the ROW performed during such semi-annual period and any updates to such ROW Development Plan.

#### 4.7.3 Decisions with Respect to Products in the ROW. Subject

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to Section 3.1.4, GSK shall have the sole discretion with respect to Development decisions for Collaboration Products for Commercialization in the ROW.

#### 4.7.4 OBD Acute Product in the ROW. The total daily dose of

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Compound (in milligrams) in the OBD Acute Product Commercialized in the ROW shall be \*\* the total daily dose of Compound (in milligrams) in the

label approved by the relevant Governmental Authority for the GI Products

Commercialized in the ROW.

4.8 Fulfillment of Obligations. It is understood that, in

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fulfilling its obligations under this Agreement, each Party shall be free to fulfill its obligations within its existing organizational structure. Upon mutual agreement of the Parties, representatives from a Party shall be entitled to attend, on an observer basis, meetings of the other Party's internal working groups responsible for the Development of the Collaboration Products.

4.9 Transfer of Data. As soon as practicable but in no event more

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than thirty (30) days after the Effective Date, the Parties shall determine what data and materials relating to Compound, GI Products and Adolor Products in the ROW are necessary for GSK's Development obligations pursuant to this Article 4, and establish a process for transferring copies of such data and material to GSK (including, to the extent available, in appropriate electronic format) or provide means of access thereto reasonably acceptable to GSK.

4.10 Right to Audit. Each Party shall use Commercially Reasonable

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Efforts to ensure that the other Party's authorized representatives, and shall ensure that Governmental Authorities, in both cases to the extent permitted by applicable Law, may, during regular business hours, (a) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions or obligations, the facilities of any subcontractor or any investigator site used by it in the performance of Development of a Collaboration Product, and (b) inspect and

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copy all data, documentation and work products relating to the activities performed by it or, subject to any Third Party confidentiality restrictions or obligations, the subcontractor or investigator site, including, without

limitation, the medical records of any patient participating in any clinical study. This right to inspect and copy all data, documentation, and work products relating to a Collaboration Product may be exercised at any time during the Term (subject to each Party's record retention policies then in effect), or such longer period as shall be required by applicable Law.

## ARTICLE 5

### CO-PROMOTION, DETAILING AND COMMERCIALIZATION

#### 5.1 U.S. Marketing Plans.

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5.1.1 General. The Joint Marketing Committee shall be responsible for

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preparing and implementing a U.S. Marketing Plan for each Collaboration Product.

Each U.S. Marketing Plan shall define the goals and objectives for Commercializing the Collaboration Products in the United States in the pertinent Calendar Year consistent with the applicable U.S. Development Plan.

5.1.2 Initial U.S. Marketing Plan for the POI Product. Within

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one-hundred fifty (150) days after the Effective Date, the Joint Marketing Committee shall prepare the U.S. Marketing Plan for the Commercialization activities for the POI Product for the \*\* and the \*\* (\*\*) Calendar Years after the projected date of First Commercial Sale of the POI Product in the United States in accordance Section 5.1.6, which such U.S. Marketing Plan shall include the minimum Detail Requirements set forth on Schedule 5.7, the minimum Marketing

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Expenses set forth on Schedule 5.1.2 and the POI Contract Product Profile.

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5.1.3 Updated U.S. Marketing Plan for the POI Product. As early as

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necessary in each Calendar Year beginning with the \*\* full Calendar Year after the Effective Date, the Joint Marketing Committee shall amend and update the U.S. Marketing Plan for the POI Product for the for the pre-launch period and the following \*\* (\*\*) Calendar Years for submission of such proposed U.S.

Marketing Plan to the Joint Steering Committee no later than \*\* of such year for review and approval.

5.1.4 U.S. Marketing Plan for OBD Chronic Product. Within \*\* (\*\*)

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days after filing the \*\* for the OBD Chronic Product, the Parties shall in good faith review and mutually agree in good faith upon the content of a U.S.

Marketing Plan for the OBD Chronic Product. If no such mutual agreement is reached, \*\*. For purposes of this Section 5.1.4, in the situation where GSK is not actively Developing or Commercializing the \*\* Product or \*\* Product in the United States, "in good faith" means that Adolor has conducted and completed such discussions with GSK on the content of such U.S. Marketing

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Plan, with Adolor waving as its primary objective retention of the OBD Chronic Product within the scope of this Agreement.

5.1.5 Initial U.S. Marketing Plans for Other Collaboration Products.

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Commencing at least \*\* (\*\*) full Calendar Years prior to the projected First Commercial Sale of a Collaboration Product (other than the POI Product), the Joint Marketing Committee will commence preparing an initial \*\* (\*\*) year U.S. Marketing Plan for such Collaboration Product for the pre-launch period and the three (3) Calendar Years after the projected date of First Commercial Sale for review and approval by the Joint Steering Committee. As early as necessary in each Calendar Year thereafter, the Joint Marketing Committee shall amend and update each U.S. Marketing Plan for such other Collaboration Products for the for the pre-launch period and the following \*\* (\*\*) Calendar Years for submission of such proposed U.S. Marketing Plan to the Joint Steering Committee no later than \*\* of such year for review and approval.

5.1.6 Contents of Each U.S. Marketing Plan. Each U.S. Marketing Plan

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shall encompass at least \*\* (\*\*) Calendar Years and shall contain at a minimum:

(a) \*\*

(b) Market research and strategy, including market size, dynamics, growth, customer segmentation, competitive analysis and Collaboration Product positioning;

(c) Annual sales forecasts;

(d) Advertising and promotion programs and strategies, including sales literature, promotional premiums, media plans, symposia and speaker programs;

(e) Sales plans and activity, including sales force training, projected Detailing in excess of the minimum Detail Requirements, where applicable, and for each Party, development of appropriate sales training materials, and strategy and budget for Samples;

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(f) Phase IV Studies to be conducted for use in the United States, which studies shall be included in the then-current U.S. Marketing Plan subject to Section 5.2.1; and

(g) Identification of the total minimum Details required to support the Collaboration Product (other than the POI Product) during such \*\*

(\*\*) Calendar Years including, where applicable in relation to any GI Product, a firm indication of the number of Sales Representatives and Details to be provided by Adolor in such period.

5.1.7 Budget for Marketing Expenses. In addition to the items

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enumerated in Section 5.1.6, each U.S. Marketing Plan shall set forth the total budget for Marketing Expenses for such Collaboration Product. Such Marketing Expense budget shall be sufficient to fund all necessary pre-launch, launch and related activities necessary to optimize Commercialization of each Collaboration Product. Notwithstanding the foregoing, unless otherwise agreed to by the Parties, the total budget for the Marketing Expenses in a Calendar Year for an Adolor Product or a GI Product for which Adolor is receiving a portion of the GI Product Marketing Contribution shall not exceed \*\* percent (\*\*%) of the budget

set forth in the most recently approved U.S. Marketing Plan for such Collaboration Product. In the event that Marketing Expenses incurred by a Party exceed the budgeted Marketing Expenses, the Party incurring such excess Marketing Expenses shall be solely responsible for such expenses unless otherwise mutually agreed in writing by the Parties.

## 5.2 Marketing Funding.

### 5.2.1 Adolor Products in the United States. Subject to reconciliation

as provided in Section 6.7.5, on an Adolor Product-by-Adolor Product basis, Adolor shall be responsible and pay for \*\* percent (\*\*%) and GSK shall be responsible and pay for \*\* percent (\*\*%) of the Marketing Expenses for each Adolor Product for Commercialization in the United States incurred from \*\* through the First Commercial Sale for such Adolor Product. Thereafter, Marketing Expenses for each Adolor Product shall be shared in accordance with the sharing of the Adolor Product Marketing Contribution for such Adolor Product as adjusted pursuant to Section 6.3.4. Notwithstanding the foregoing, if a \*\* Study for an Adolor Product is not commenced earlier than \*\* (\*\*) years prior to the expiration of the Adolor Product Promotion Term and such \*\* Study has no applicability to a Collaboration Product in any Country in the ROW, Adolor shall be responsible and pay for \*\* (\*\*) of any such \*\* Study.

### 5.2.2 OBD Chronic Product in the United States. Subject to

reconciliation as provided in Section 6.7.5, Adolor shall be responsible and pay for \*\* percent (\*\*%) and GSK shall be responsible and pay for \*\* percent (\*\*%) of the Marketing Expenses in connection with the OBD Chronic Product for Commercialization in the United States incurred from the Effective Date through \*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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the First Commercial Sale for such OBD Chronic Product. Thereafter, Marketing Expenses for the OBD Chronic Product shall be shared in accordance with the



sharing of the GI Product Marketing Contribution for such OBD Chronic Product as adjusted pursuant to Section 6.3.4. Notwithstanding the foregoing, upon notice by Adolor to GSK of a Royalty Conversion Election, GSK shall be solely responsible and pay for all Marketing Expenses relating to periods after such notice for the OBD Chronic Product for which the Royalty Conversion Election was made.

#### 5.2.3 Other GI Products in the United States. Provided that Adolor

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elects to fund Development Expenses for a GI Product (other than the OBD Chronic Product) pursuant to Section 4.6.5 and subject to reconciliation as provided in Section 6.7.5, Adolor shall, from and after the date of such election, be responsible and pay for \*\* percent (\*\*%) and GSK shall be responsible and pay for \*\* percent (\*\*%) of the Marketing Expenses for such GI Product (other than the OBD Chronic Product) in the United States until the First Commercial Sale occurs for such GI Product. Thereafter, Marketing Expenses for a GI Product (other than the OBD Chronic Product) shall be shared in accordance with the sharing of the GI Product Marketing Contribution for such GI Product (other than the OBD Chronic Product) as adjusted pursuant to Section 6.3.4. Notwithstanding the foregoing, upon notice by Adolor to GSK of a Royalty Conversion Election, GSK shall be solely responsible and pay for all Marketing Expenses relating to periods after such notice for such GI Product for which the Royalty Conversion Election was made.

#### 5.2.4 Marketing Expenses Incurred for the POI Product in the United

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States. Unless otherwise agreed to by the Joint Marketing Committee, all

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Marketing Expenses for the POI Product shall be incurred by Adolor, subject to reimbursement as provided for herein.

#### 5.3 Implementation of U.S. Marketing Plans. In implementing a U.S.

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Marketing Plan, each Party will develop and maintain appropriate liaison with the Joint Marketing Committee to resolve any questions regarding such implementation and to communicate to the Joint Marketing Committee timely suggestions for improving the U.S. Marketing Plan. In connection with the

preparation and implementation of the U.S. Marketing Plan, Adolor and GSK will make available to the Joint Marketing Committee marketing intelligence and market research information then in their possession pertaining to the Collaboration Products, the usage of the Collaboration Products and market trends.

#### 5.4 Obligations for Commercialization.

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##### 5.4.1 General. The Parties shall use \*\* to Commercialize the

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Collaboration Products.

##### 5.4.2 GSK's Obligations. In furtherance of the foregoing, and subject

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to GSK's termination rights pursuant to Article 16 (including those safety related

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termination rights pursuant to Section 16.4), GSK may not, either individually or as a member of the Joint Steering Committee:

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#### 5.5 Commercialization Responsibilities.

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##### 5.5.1 Adolor Responsibilities.

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(a) Adolor shall have the sole right and responsibility to record and collect payment for sales of Adolor Products throughout the United States.

(b) Adolor shall use its Commercially Reasonable Efforts to employ an appropriate management infrastructure to supervise the Sales Representatives required to oversee Adolor's obligations to perform Detail Requirements and marketing staff of sufficient size to establish, maintain and implement the U.S. Marketing Plan for the Adolor Products.

(c) In the event Adolor has not made a Royalty Conversion

Election for the OBD Chronic Product or another GI Product where Adolor has elected to fund Development Expenses under Section 4.6.5, Adolor, \*\*, may engage Adolor Sales Representatives to Detail the relevant GI Product. In such event, Adolor and GSK shall negotiate in good faith the minimum number of Details to be conducted by the Parties to be included in the relevant U.S. Marketing Plan; provided, however, in the event that Adolor elects to Detail such a GI Product, Adolor must perform at least, and GSK shall not require Adolor to perform more than, \*\* percent (\*\*%) of the total Detail Requirements for such GI Product.

#### 5.5.2 GSK Responsibilities.

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(a) GSK shall have the sole right and responsibility to record and collect payment for sales of GI Products throughout the United States.

(b) GSK will be responsible for storage, order receipt, order fulfillment, shipping and invoicing of Collaboration Products. In the case of Adolor Products in the United States, invoices shall be for the account of Adolor using an acceptable Adolor invoicing form and Adolor letterhead. The Joint Marketing Committee shall establish mechanisms for real-time data

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exchange, invoicing schedules, credit control and other necessary standard operating procedures relating to the invoicing for the account of Adolor.

(c) In addition to the Detailing Requirements, GSK, at its sole expense, commencing \*\* (\*\*) months after the NDA Acceptance, and on an annual basis for the period of the Adolor Product Promotion Term, shall provide, at a minimum, the marketing and sales support for the POI Product as set forth on Schedule 5.5.2.

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(d) GSK shall have the sole right and responsibility to distribute, sell, record sales and collect payments for Collaboration Products in the ROW during the ROW Term.

(e) GSK shall have sole responsibility for establishing and modifying the terms and conditions with respect to the sale of Collaboration Products in the ROW, including, without limitation, the price or prices at which the Collaboration Products in the ROW will be sold, any discount applicable to payments or receivables, and similar matters.

(f) Within \*\* (\*\*\*) days after \*\* for the POI Product, GSK will be responsible, at the direction of the Joint Marketing Committee, for developing and implementing the healthcare insurance company and third party payor reimbursement strategy for the Collaboration Products; provided, however, that within \*\* (\*\*\*) days after the \*\* anniversary of the First Commercial Sale of the POI Product and subject to the approval of the Joint Marketing Committee, Adolor may assume responsibility for such activities for any or all of the Adolor Products; provided further that such assumption of responsibilities by Adolor will not have a material adverse effect on the sales in the United States of the POI Product.

#### 5.5.3 Conditions for Sales of Collaboration Products in the

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United States. The Joint Marketing Committee shall establish and modify

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conditions of sale of Collaboration Products to Third Parties in the United States, including, without limitation, the price or prices at which the Collaboration Products in the United States will be sold, any discount applicable to payments or receivables, and similar matters.

#### 5.6 Detailing Efforts. The Parties shall market, Detail and

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Co-Promote the Collaboration Products in the United States in accordance with the terms of this Agreement and the relevant U.S. Marketing Plan. No Party shall be required to undertake any activity under this Agreement which it believes, in good faith, would violate any Laws. GSK shall use Commercially Reasonable Efforts to perform its annual Detail Requirements \*\* in each Calendar Quarter.

\*\* . In any Calendar Year, no more than \*\* of all Detail Requirements of a

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Party for a GI Product in the United States, where Adolor has elected to fund Development Expenses under Section 4.6.5 and has not made a Royalty Conversion Election, shall be made by Specialist Sales Representatives.

#### 5.7 Detailing and Marketing Requirements. The Joint Marketing

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Committee shall determine the targeted number of total Details and Primary Details to be performed by each Party in the United States during each Calendar Year and the Target Audience for such Details (the "Detail Requirements"); \*\*.

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#### 5.8 Sales Force Incentive Compensation for POI Products. Each

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Party shall offer incentive compensation to its Sales Representatives with respect to the sale of the POI Product in the United States for each Calendar Year during the Adolor Product Promotion Term. Such incentive schemes shall be adopted by each Party in a manner consistent with the way other incentive schemes are adopted within their respective organizations; provided, however, that \*\*

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\*\* . Each Party shall notify the other Party, prior to the First Commercial Sale and prior to the commencement of each Calendar Year thereafter, of the structure, formula and relative competitiveness of such arrangement (having regard to other such arrangements adopted by GSK, Adolor, or other companies in the pharmaceutical industry for a company similar in size and scope to such Party).

#### 5.9 Detailing Reports.

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5.9.1 Reports. Within thirty (30) days following the end of

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each Calendar Quarter, each Party shall provide the Joint Marketing Committee with a report setting forth, in such detail and form as the Joint Marketing Committee shall require (the "Internal Detailing Report"), based upon each

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Party's internal Call reporting and Detailing auditing system, the total number of Details, Major Details and Secondary Details actually performed by such Party, in the United States, segmented by physician specialty of the Target Audience during the immediately preceding Calendar Quarter.

#### 5.9.2 Records and Audits Pertaining to Details. At any time

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during the Term of this Agreement, but not more than twice every Calendar Year, each Party agrees to make available to the auditing Party, upon reasonable advance notice, such books and records necessary to verify the accuracy of such Internal Detailing Report with respect to any Calendar Quarter ending not more than twelve (12) Calendar Quarters prior to the date of such request. Unless the auditing Party has notified the other Party of an issue relating to verifying an Internal Detailing Report for a particular Calendar Quarter, such other Party shall be released from any liability or accountability to the auditing Party for Detailing in any Calendar Quarter ending more than twelve (12) Calendar Quarters prior to the initiation of such verification process by the auditing Party. In the event of an unresolved dispute regarding the number of Details actually performed by a Party based on such Party's internal Call reporting and Detail auditing system, the Parties hereby agree that such Party's internal Call reporting and Detail auditing system may be correlated (on a trend basis only) with the Dispute Detailing Audit Data. Such correlation may be used by the auditing Party in any court or arbitration proceeding with respect to any dispute regarding Detailing under this Agreement.

#### 5.10 Training.

##### 5.10.1 Training Plans. The Joint Marketing Committee shall

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develop training plans at least \*\* (\*\*) days \*\* a Collaboration Product. GSK and Adolor shall, each at its own expense, comply with the training plan contained in any U.S. Marketing Plan which is otherwise consistent with provisions of this

Agreement. Each Party will be responsible for

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supervising, training and maintaining its Sales Representatives as may be required to Detail the Collaboration Products as provided herein or in the applicable U.S. Marketing Plan, such training to include a reasonable proficiency examination relevant to the Collaboration Products given at least annually for all Sales Representatives who will be engaged in Detailing, at such Party's own cost and expense. Adolor shall have the right to participate in the training programs of GSK, and GSK shall have the right to participate in the training programs of Adolor, for the purpose of ensuring overall consistency in the training programs for the Collaboration Products.

5.10.2 Assistance. During the United States Term, each Party

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shall make available to the other for use in connection with Co-Promoting the Collaboration Products in the United States, to the extent reasonable, assistance and services relating to such Co-Promotion, including, but not limited to, providing the other Party, free of charge and in a timely manner, with a master copy of such training materials relating to Collaboration Products as such Party has used and/or intends to use in connection with the training of its Sales Representatives, including but not limited to learning units and any other printed, audio and video training materials. To the extent the other Party wishes to use such training materials in the training of its own Sales Representatives, it will be responsible for reproducing such training materials.

5.10.3 Training of Sales Representatives. All Sales

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Representatives of a Party have received, or will receive in a timely manner, appropriate training on proper marketing and sales techniques to be used in promoting pharmaceutical products in accordance with applicable Laws.

5.10.4 Joint Marketing and Sales Meetings. The Parties shall

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plan and implement periodic joint sales and marketing meeting, including a national launch meeting, for each Adolor Product, and the OBD Chronic Product and each other GI Product where Adolor has elected to fund Development Expenses under Section 4.6.5 and where Adolor has not made a Royalty Conversion Election, in the United States. Costs and expenses attributable to individual attendees of each Party, such as lodging and transportation, shall be borne by such Party and shall not be deemed a Marketing Expense. All other expenses associated with such meetings shall be deemed \*\*.

#### 5.11 Commercialization in the ROW.

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5.11.1 GSK Responsibility. GSK shall have sole responsibility

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for Commercialization of Collaboration Products for distribution and sale in the ROW. \*\*, GSK shall bear all costs and expenses associated with the Commercialization of Collaboration Products for sale or distribution in the ROW.

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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#### 5.11.2 Coordination; Semi-Annual Reports.

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(a) GSK shall coordinate through the Joint Steering Committee the Commercialization of Collaboration Products in the ROW with the Commercialization of Collaboration Products in the United States with the objective of coordination of global product positioning and sharing of best practices and strategies.

(b) GSK shall provide the Joint Steering Committee reports semi-annually. Such reports shall set forth in summary form the results of GSK's Commercialization activities performed during such semi-annual period.

(c) No later than \*\* of each Calendar Year, GSK shall provide to Adolor in writing a good faith estimate of the projected Net Sales by Calendar Quarter on a Country-by-Country basis for the Major Market Countries, and a summary for the remainder of the ROW, of each Collaboration Product for at



least \*\* (\*\*) full Calendar Years after the anticipated First Commercial Sale of such Collaboration Product (the "ROW Net Sales Forecast").

GSK shall update each ROW Net Sales Forecast on a semi-annual basis. For the POI Product in the ROW, the first ROW Net Sales Forecast shall be furnished to Adolor within one hundred twenty (120) days after the Effective Date. For each Collaboration Product (other than the POI Product) in the ROW, the first ROW Net Sales Forecast shall be furnished to Adolor at least \*\* (\*\*) full Calendar Years prior to the projected First Commercial Sale in the ROW of such Collaboration Product.

#### 5.11.3 Decisions with Respect to Collaboration Products in

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the ROW. GSK shall have the sole discretion with respect to Commercialization

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decisions for Collaboration Products in the ROW subject to Section 3.1.4(b) and provided that GSK takes into account on a global basis the goal of realizing the best overall commercial potential of the Products.

#### 5.11.4 Exports to the United States. The Parties shall use

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Commercially Reasonable Efforts to prevent the Collaboration Products distributed for sale in a particular Country other than the United States from being exported to the United States for sale.

### ARTICLE 6

#### FINANCIAL PROVISIONS

##### 6.1 Upfront Payment. In partial consideration for the acquisition

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of license rights under the Adolor Patents and the Adolor Know-How by GSK under this Agreement, GSK shall, within \*\* (\*\*) Business Days after the Effective Date, pay to Adolor a non-creditable, non-refundable amount of fifty million United States Dollars (US \$50,000,000) and Adolor shall issue GSK on the Effective Date the invoice therefor attached hereto as Schedule 6.1.

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## 6.2 Milestone Payments.

### 6.2.1 In further consideration of the acquisition of license

rights under Adolor Patents and the Adolor Know-How by GSK under this Agreement, GSK shall also pay to Adolor the payments set forth in Schedule 6.2 for each

such Development milestone referred to therein (each, a "Development

Milestone"); provided always that each such payment shall be made only one time

for each Collaboration Product in accordance with Schedule 6.2 regardless of how

many times such Development Milestones are achieved for such Collaboration Product, and no payment shall be owed for a Development Milestone which is not reached (except that, upon achievement of a Development Milestone for a particular Collaboration Product, any previous Development Milestone for that Collaboration Product for which payment was not made shall be deemed achieved and payment therefor shall be made); provided further that, in the event that more than one Development Milestone is achieved with respect to the same Collaboration Product at one time or from time to time, then all applicable payments under Schedule 6.2 shall be made to Adolor. By way of example, if the

\*\* Product and the \*\* Product are approved in the same Marketing Authorization Approval, then, in addition to the relevant milestone for the \*\* Product, the relevant milestone for the \*\* Product shall be paid simultaneously.

6.2.2 In the event a Party achieves a Development Milestone, such Party shall promptly, but in no event more than five (5) days after the achievement of each such Development Milestone, notify the other Party in writing of the achievement of same. For all Development Milestones achieved, GSK shall promptly, but in no event more than thirty (30) days after the achievement of each such Development Milestone, remit payment to Adolor for such Development Milestone.

6.3 Marketing Contribution for Collaboration Products.

6.3.1 Share of Adolor Product Marketing Contribution. During

the period beginning with the First Commercial Sale of each Adolor Product and ending on the last day of the Calendar Quarter in which the \*\* anniversary of such First Commercial Sale occurs (the "Initial \*\* Year Period"), Adolor shall

receive \*\* percent (\*\*%) and GSK shall receive \*\* percent (\*\*%) of the Adolor Product Marketing Contribution of such Adolor Product, subject to adjustment as set forth in Section 6.3.4 and reconciliation as set forth in Section 6.7.5.

After the Initial \*\* Year Period, each Party shall receive \*\* percent (\*\*%) of the Adolor Product Marketing Contribution for such Adolor Product, subject to adjustment as set forth in Section 6.3.4 and reconciliation as set forth in Section 6.7.5.

6.3.2 Share of GI Product Marketing Contribution. For the OBD

Chronic Product and for any other GI Product where Adolor has elected to fund Development Expenses pursuant to Section 4.6.5, and provided further that Adolor has not made a Royalty Conversion Election as provided in Section 6.3.5, Adolor shall

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receive \*\* percent (\*\*%) and GSK shall receive \*\* percent (\*\*%) of the GI Product Marketing Contribution for a GI Product, subject to adjustment as set forth in Section 6.3.4 and reconciliation as set forth in Section 6.7.5.

6.3.3 Compensation for Distribution Services. GSK shall

receive \*\* percent (\*\*%) of Net Sales in the United States as the sole compensation to GSK for the services to be provided in the United States pursuant to Section 5.5.2(b) (the "Distribution Services Fee") for Adolor

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Products and for GI Products where Adolor funds Development of such GI Product and has not made a Royalty Conversion Election, which amount shall be paid in accordance with this Article 6. Within one hundred eighty (180) days after the Effective Date, the Parties shall negotiate in good faith a distribution services agreement with respect to the foregoing.

#### 6.3.4 Adjustment of Marketing Contribution. On a Collaboration

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Product-by-Collaboration Product basis, in the event that a Party only performs between \*\* percent (\*\*%) and \*\* percent (\*\*%) of its Detail Requirements (measured for both its total Details and Primary Details) in a Calendar Year (the "Defaulting Party"), then the Defaulting Party's share of the Adolor

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Product Marketing Contribution or GI Product Marketing Contribution, as applicable, for such Calendar Year shall be reduced by \*\* percentage (\*\*%) points and the other Party's share of the Adolor Product Marketing Contribution or the GI Product Marketing Contribution, as applicable, for such Calendar Year shall be correspondingly increased. In the event the Defaulting Party performs less than \*\* percent (\*\*%) of its Detail Requirements (measured for both its total Details and Primary Details) for a Collaboration Product in such Calendar Year, then, in addition to the \*\* percentage (\*\*%) point reduction, the Defaulting Party's share of the Adolor Product Marketing Contribution or GI Product Marketing Contribution, as applicable, for such Calendar Year shall also be reduced \*\* percentage (\*\*%) \*\* for each \*\* percentage (\*\*%) \*\* that the Defaulting Party's actual number of Details is less than \*\* percent (\*\*%) of the Defaulting Party's Detail Requirements (measured for both its total Details and Primary Details) and the other Party's share of the Adolor Product Marketing Contribution or the GI Product Marketing Contribution, as applicable, for such Calendar Year shall be correspondingly increased. If a Party is a Defaulting Party for a Collaboration Product for \*\* (\*\*) \*\*, then the Adolor Product Marketing Contribution or the GI Product Marketing Contribution, as applicable, shall be permanently reduced and correspondingly increased for the other Party, by an amount equal to the average of the adjustments made for the \*\* (\*\*) \*\*. In the event that a Party fails to perform at least \*\* percent (\*\*%) of its Detail

Requirements (measured for both its total Details and Primary Details) for a Collaboration Product in a Calendar Year, that Party shall be deemed to have materially breached this Agreement and such breach shall be deemed incurable.

For purposes of this Section, the determination as to whether GSK has met its minimum Detail Requirements shall be made with respect to both its Detail Requirements to \*\* as a Target Audience and to GSK's total

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Detail Requirement. The provisions of this Section 6.3.4 shall apply even if both Parties are a Defaulting Party.

6.3.5 Conversion to Royalty. On a GI Product-by-GI Product basis,

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within \*\* (\*\*) days \*\* for such GI Product, and within \*\* (\*\*) months after each \*\* (\*\*) year anniversary thereafter, Adolor shall have the right to convert its right to receive a percentage of the GI Product Marketing Contribution to a royalty, as set forth in Section 6.4.2 (the "Royalty Conversion Election"). The

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Royalty Conversion Election shall be made in writing, and shall be irrevocable once made. Upon making the Royalty Conversion Election, Adolor shall have no further obligation to fund or otherwise be responsible for any expenses relating to such GI Product for any time periods following the delivery of the Royalty Conversion Election.

6.4 Payment of Royalties on Net Sales in the ROW.

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6.4.1 Within thirty (30) days after the end of each Calendar Quarter, GSK shall pay Adolor royalty payments based on Net Sales in such Calendar Quarter in the ROW during the ROW Term as follows: (a) \*\* percent (\*\*%) for GI Products; and (b) \*\* percent (\*\*%) for Adolor Products. The royalty payments made under this Section 6.4.1 shall be based on actual Net Sales for the first two (2) months of a Calendar Quarter and an estimate for the third month of the Calendar Quarter based upon projected Net Sales. Within sixty (60) days after

the end of each Calendar Quarter, GSK shall calculate the actual amount of Net Sales for the third month of such Calendar Quarter and either credit or debit the difference between such actual and projected amount on the succeeding Calendar Quarter's royalty payment to Adolor.

6.4.2 For Collaboration Products in the ROW where there is Generic Competition and where the ROW Term has not expired pursuant to Section 1.125(a) or 1.125(b), on a Country-by-Country and Collaboration Product-by-Collaboration Product basis, royalty rates shall be reduced by \*\* percent \*\*.

#### 6.5 Payment of Royalties on Net Sales of GI Products in the United

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States. Within thirty (30) days after the end of each Calendar Quarter, GSK

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shall pay Adolor royalty payments based on Net Sales in such Calendar Quarter in the United States during the GI Product Promotion Term as follows: (a) \*\* ( \*\* %) for GI Products where Adolor has not elected to fund Development Expenses for such GI Product; and (b) \*\* percent ( \*\* %) for the OBD Chronic Product, and other GI Products where Adolor has elected to fund Development Expenses for such GI Product and subsequently made a Royalty Conversion Election; provided that if the First Commercial Sale in the United States for the OBD Chronic Product has not occurred prior to the First Commercial Sale in the United States of either the \*\* Product or the \*\* Product, then the royalty rate on such \*\* Product or \*\* Product shall be \*\* (\*\*%) regardless of whether Adolor has funded Development Expenses for such GI Product; provided further that if the OBD Chronic Product is subsequently launched and Adolor has not elected to fund Development Expenses for the \*\* Product and \*\*

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Product the royalty rate on such \*\* Product or \*\* Product shall thereafter be reduced to \*\* (\*\*%). The royalty payments made under this Section 6.5 shall be based on actual Net Sales for the first two (2) months of a Calendar Quarter and an estimate for the third month of the Calendar Quarter based upon projected Net

Sales. Within sixty (60) days after the end of each Calendar Quarter, GSK shall calculate the actual amount of Net Sales for the third month of such Calendar Quarter and either credit or debit the difference between such actual and projected amount on the succeeding Calendar Quarter's royalty payment to Adolor.

#### 6.6 Royalty Responsibilities; Net Sales Reports.

##### 6.6.1 Payments to Third Parties.

(a) Adolor shall pay any amounts owed Lilly and Shire as a result of the use of the Adolor Patents or Adolor Know-How with respect to sales of Collaboration Products. Any royalties paid to Lilly and Shire pursuant to this Section 6.6.1(a) shall be subject to reconciliation pursuant to Section 6.7.5.

(b) GSK shall pay any amounts owed to a Third Party, other than to Lilly and Shire, as a result of the use of the Adolor Patents or Adolor Know-How (i) with respect to sales of GI Product in the United States on which Adolor is receiving a royalty and Collaboration Products in the ROW and shall deduct such amounts from Net Sales in such Country prior to calculating royalties owed to Adolor and (ii) with respect to sales of GI Products in the United States where Adolor has elected to fund Development Expenses under Section 4.6.5, in each case where Adolor has not made a Royalty Conversion Election, and subject to reconciliation pursuant to Section 6.7.5.

(c) The Parties shall each be responsible for \*\* percent (\*\*%) of royalty amounts, if any, owed to a Third Party relating to \*\* (except for any royalty amounts pursuant to subsection (a) above) subject to reconciliation pursuant to Section 6.7.5.

(d) GSK shall pay any amounts owed to a Third Party other than as set forth in Section 6.6.1(a), 6.6.1(b) or 6.6.1(c) (i) with respect to sales of GI Products in the United States for which Adolor is receiving a royalty and Collaboration Products in the ROW and shall not deduct such amounts from Net Sales prior to calculating royalties owed to Adolor and (ii) with respect to sales of the OBD Chronic Product in the United States and other GI Products in the United States where Adolor has elected to fund Development Expenses under Section 4.6.5, in each case where Adolor has not made a Royalty Conversion

Election, and subject to reconciliation pursuant to Section 6.7.5.

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6.6.2 Net Sales Report. Within thirty (30) days after the end of each

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Calendar Quarter, GSK shall submit to Adolor a written report setting forth Net Sales in the ROW and the United States (but only if Adolor is receiving royalty payments based on sales in the United States) on a Country-by-Country and Collaboration Product-by-Collaboration Product basis during such Calendar Quarter, total royalty payments due Adolor, relevant market share data supporting the presence of Generic Competition, if any, and any payments made to any Third Party pursuant to Section 6.6.1 (each a "Net Sales Report").

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6.6.3 Basis for Royalty Payment. The Parties acknowledge that the

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royalty payments provided for in Sections 6.4 and 6.5 are intended to provide appropriate economic benefits to Adolor in recognition for \*\*.

6.7 Reports.

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6.7.1 Estimate Reports. Within ten (10) days after the end of each

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Calendar Quarter, GSK shall prepare and deliver to Adolor a report for internal accounting purposes setting forth GSK's good faith estimate of Net Sales of GI Products In the United States and Collaboration Products in the ROW and Adolor's share of the GI Product Marketing Contribution. Within ten (10) days after the end of each Calendar Quarter, Adolor shall prepare and deliver to GSK a report for internal accounting purposes setting forth Adolor's good faith estimate of Net Sales of Adolor Products and GSK's share of the Adolor Product Marketing Contribution.

6.7.2 GSK Report. Within forty-five (45) days after the end of each

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Calendar Quarter, on a Collaboration Product-by-Collaboration Product basis in the United States, GSK shall submit to Adolor a written report (each, a "GSK

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Report") setting forth in reasonable detail the following items during such

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Calendar Quarter:

- (a) Development Expenses incurred by GSK for each: (i) Adolor Product; and (ii) GI Product for which Adolor will receive a percentage of GI Product Marketing Contribution;
- (b) Marketing Expenses incurred by GSK for each: (i) Adolor Product; and (ii) the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election;
- (c) Cost of Goods for the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election (except for any \*\* under a supply agreement between the Parties);
- (d) API Compound Carrying Cost;

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- (e) Royalties, if any, paid by GSK to Third Parties in accordance with Section 6.6.1;
- (f) Detail Costs for the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election; and
- (g) Net Sales of Collaboration Products in the United States and the ROW.

6.7.3 Adolor Report. Within forty-five (45) days after the end of

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each Calendar Quarter, on a Collaboration Product-by-Collaboration Product basis in the United States, Adolor shall submit to GSK a written report (each, an

"Adolor Report") setting forth in reasonable detail the following items during

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such Calendar Quarter:

- (a) Development Expenses incurred by Adolor for each: (i) Adolor Product; and (ii) the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election;
- (b) Marketing Expenses incurred by Adolor for each: (i) Adolor Product; and (ii) the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election;
- (c) Cost of Goods for each Adolor Product in the United States (except for any Cost of Goods separately reimbursed under a supply agreement between the Parties);
- (d) Royalties, if any, paid by Adolor to Third Parties in accordance with Section 6.6.1;
- (e) API Compound Carrying Cost;
- (f) Detail Costs for the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election; and
- (g) Net Sales of Adolor Product in the United States.

6.7.4 Reimbursements. In conjunction with the reconciliation set

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forth in Section 6.7.5:

- (a) Adolor shall reimburse GSK: (i) \*\* percent (\*\*%) of Marketing Expenses, Cost of Goods (except for any Cost of Goods separately reimbursed under a supply agreement between the Parties), Distribution Services Fees and royalties to Third Parties, in each case paid or incurred by GSK with respect to Adolor Products sold in the United States for which Adolor is recording sales and collecting payments; and

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(ii) API Compound Carrying Cost incurred by GSK for all Collaboration Products.

(b) GSK shall reimburse Adolor: (i) \*\* percent (\*\*%)

of Marketing Expenses, Cost of Goods (except for any Cost of Goods separately reimbursed under a supply agreement between the Parties) and royalties to Third Parties, in each case paid or incurred by Adolor with respect to GI Products sold in the United States for which GSK is recording sales and collecting payments; (ii) API Compound Carrying Cost incurred by Adolor for all Collaboration Products; and (iii) Detail Costs for the actual Details performed by Adolor for the OBD Chronic Product and each other GI Product for where Adolor has elected to fund Development Expenses under Section 4.6.5, and where Adolor has not made a Royalty Conversion Election.

(c) The Parties shall determine the total Development Expenses for the relevant reporting period and shall effect the reimbursement of the Development Expenses as necessary consistent with each Party's share of such Development Expenses pursuant to Section 4.6.

#### 6.7.5 Financial Reconciliation.

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(a) Within sixty (60) days after the end of each Calendar Quarter, commencing with first Calendar Quarter during which the Effective Date occurs (which shall include all periods since January 1, 2002, Adolor shall, using the GSK Report and the Adolor Report, prepare a reconciliation report for Adolor Products in the United States (the "Adolor Reconciliation Report") which

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shall show the Development Expenses either Party may owe the other, the calculation of the Adolor Product Marketing Contribution, each Party's share of the Adolor Product Marketing Contribution, the reimbursements owed to GSK pursuant to Section 6.7.4(a), and the resulting net amount owed by Adolor to GSK or by GSK to Adolor as the case may be, in each case for Adolor Products in the United States. Within twenty (20) days after receipt by GSK of the Adolor Reconciliation Report, GSK or Adolor, as the case may be, shall pay the net amount shown therein to the other Party.

(b) Within sixty (60) days after the end of each Calendar Quarter, commencing with the first Calendar Quarter following the Effective

Date, GSK shall, using the GSK Report and the Adolor Report, prepare a reconciliation report for GI Products in the United States (the "GSK

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Reconciliation Report") which shall show the Development Expenses either Party

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may owe the other, the calculation of the GI Product Marketing Contribution, each Party's share of the GI Product Marketing Contribution, the reimbursements owed to Adolor pursuant to Section 6.7.4(b) and the resulting net amount owed by Adolor to GSK or by GSK to Adolor as the case may be, in each case for GI Products in the United

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States. Within twenty (20) days after receipt by Adolor of the GSK Reconciliation Report, GSK or Adolor, as the case may be, shall pay the net amount shown therein to the other Party.

6.8 Payment Upon Expiration of the Adolor Product Promotion Term.

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6.8.1 If the Adolor Product Promotion Term expires on the \*\* (\*\*) anniversary of the First Commercial Sale of the POI Product in the United States, Adolor shall pay GSK an amount equal to the sum of: \*\*.

6.8.2 If the Adolor Product Promotion Term expires on the \*\* (\*\*) anniversary of the First Commercial Sale of the POI Product in the United States, Adolor shall pay GSK an amount equal to \*\*.

6.8.3 No payment shall be made pursuant to this Section 6.8 if the Adolor Product Promotion Term expires after the \*\* (\*\*) anniversary of the First Commercial Sale of the POI Product or is terminated prior to the expiration of the Adolor Product Promotion Term.

6.9 GAAP. All financial terms and standards defined or used in this

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Agreement for sales or activities occurring in the United States shall be governed by and determined in accordance with United States generally accepted

accounting principles, consistently applied. Except as otherwise set forth herein, all financial terms and standards defined or used in this Agreement for sales or activities occurring in the ROW shall be governed by and determined in accordance with United Kingdom generally accepted accounting principles, consistently applied.

6.10 Currencies. Payments under this Agreement shall be made in United

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States Dollars. Revenues and expenses for each Country shall be converted into United States Dollars using the applicable exchange rate for converting such local currency to the United States Dollar in accordance with the exchange rates used by GSK in producing its financial accounts at the time and detailed in its annual report as agreed by its auditors.

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6.11 Manner of Payments. All sums due to either Party under this Article 6

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shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) as each of GSK and Adolor shall designate. GSK shall notify Adolor as to the date and amount of any such wire transfer to Adolor at least two (2) Business Days prior to such transfer. Adolor shall notify GSK as to the date and amount of any such wire transfer to GSK at least two (2) Business Days prior to such transfer.

6.12 Interest on Late Payments. If either Adolor or GSK shall fail to make

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a timely payment pursuant to this Article 6, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable law, at the average one-month London Inter-Bank Offering Rate (LIBOR) for the United States Dollar as reported from time to time in The Wall Street Journal, effective for the first date on which payment was delinquent and calculated on the number of days such payment is overdue or, if such rate is not regularly published, as published in such

source as the Joint Steering Committee agrees.

6.13 Tax Withholding. Any taxes, levies or other duties ("Taxes") paid or

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required to be withheld under the appropriate local tax laws by one of the

Parties ("Withholding Party") on account of monies payable to the other Party

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under this Agreement shall be deducted from the amount of monies otherwise

payable to the other Party under this Agreement. The Withholding Party shall

secure and send to the other Party within a reasonable period of time proof of

any such Taxes paid or required to be withheld by Withholding Party for the

benefit of the other Party. The Parties shall cooperate reasonably with each

other to ensure that any amounts required to be withheld by either Party are

reduced in amount to the fullest extent permitted by Law. No deduction shall be

made, or a reduced amount shall be deducted, if the other Party furnishes a

document from the appropriate tax Governmental Authorities to the Withholding

Party certifying that the payments are exempt from Taxes or subject to reduced

tax rates, according to the applicable convention for the avoidance of double

taxation.

6.14 Financial Records; Audits. Each Party shall keep, and shall cause its

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Affiliates and sublicensees to keep, such accurate and complete records of Net

Sales and its Marketing Expenses and Development Expenses as are necessary to

determine the amounts due to GSK and Adolor under this Agreement. Such records

shall be retained by each Party or any of its Affiliates or sublicensees (in

such capacity, the "Recording Party"). During normal business hours and with

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reasonable advance notice to the Recording Party, such records shall be made

available for inspection, review and audit, at the request and expense of the

other Party (the "Auditing Party"), by an independent certified public

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accountant, or the local equivalent, appointed by such Auditing Party and

reasonably acceptable to the Recording Party for the sole purpose of verifying

the accuracy of the Recording Party's accounting reports and payments made or to

be made pursuant to this Agreement; provided, however that such audits may not

be performed by the Auditing Party more than once per Calendar Year and that such Auditing Party shall not be permitted to audit the same period of time more than once. Such accountants shall be instructed not to reveal to the Auditing Party the details of its review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants' conclusions to

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the Auditing Party, and all such information shall be deemed Confidential Information of the Recording Party; provided, however, that in any event such information may be presented to the Auditing Party in a summary fashion as is necessary to report the accountants' conclusions. All costs and expenses incurred in connection with performing any such audit shall be paid by the Auditing Party unless the audit discloses at least a \*\* percent (\*\*%) shortfall, in which case the Recording Party will bear the full cost of the audit for such Calendar Year. The Auditing Party will be entitled to recover any shortfall in payments due to it as determined by such audit, plus interest thereon calculated in accordance with Section 6.12, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it against payments the Auditing Party is otherwise required to make to the Reporting Party under this Agreement. The documents from which were calculated the sums due under this Article 6 shall be retained by the relevant Party during the United States Term or the ROW Term, as applicable.

## ARTICLE 7

### PROMOTIONAL MATERIALS AND SAMPLES

#### 7.1 Promotional Materials.

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##### 7.1.1 Creation of United States Promotional Materials. Subject to the

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terms of Section 7.1.2 and applicable Law, for Adolor Products during the Adolor Product Promotion Term and for GI Products during the GI Product Promotion Term, in accordance with the direction of the Joint Marketing Committee, the Parties will jointly, through consultation and with the assistance of each other, create and develop Promotional Materials for the United States. GSK may use the

Promotional Materials for the United States as the promotional materials in the ROW or GSK shall, subject to Sections 3.1.4(b) and 3.3.2, create and develop promotional materials suitable for use in the ROW.

#### 7.1.2 Adolor Ownership of United States Promotional Materials.

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Subject to the terms of this Section 7.1, Adolor shall own all right, title and interest in and to any Promotional Materials relating to the Adolor Products in the United States, including without limitation applicable copyrights and trademarks, and GSK hereby assigns all its right, title and interest to such Promotional Materials to Adolor and agrees to execute all documents and take all actions as are reasonably requested by Adolor to vest title to such Promotional Materials in Adolor in the United States.

#### 7.1.3 GSK Ownership of United States and ROW Promotional Materials.

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Subject to the terms of this Section 7.1, GSK shall own all right, title and interest in and to any Promotional Materials relating to GI Products in the United States and to any promotional materials relating to Collaboration Products in the ROW, including without limitation applicable copyrights and trademarks, and Adolor hereby assigns all its right, title and interest to such materials to GSK and agrees to execute all documents and take all actions as are reasonably requested by GSK to vest title to such materials in GSK.

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#### 7.1.4 Retention of Rights. GSK and Adolor, or their respective

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Affiliates, shall retain all rights, including without limitation all copyrights and trademarks, to all of their respective existing programs and materials in all formats (print, video, audio, digital, computer, etc.) regarding sales training, patient education and disease management programs owned by each at the time such materials are shared with the other Party, as well as any modifications of such programs each may develop in the future which are not



specific to a Collaboration Product. GSK and Adolor shall, from time to time, each notify the other as to the identity of such proprietary programs that may be relevant for purposes of this Agreement. In the event that Adolor desires after the expiration or termination of this Agreement, to use any GSK program which has been specifically adapted for, or directed to, a Collaboration Product under this Agreement, the Parties shall negotiate in good faith to conclude, if possible, an appropriate agreement under which Adolor would be permitted to engage in such continued use (including without limitation the amount of compensation to be paid to GSK for such use). In addition, all such new programs hereafter jointly developed by GSK and Adolor pursuant to this Agreement shall be jointly owned by GSK and Adolor, and each Party shall have the right to use such jointly developed programs free of charge after the Term, subject to the remaining obligations imposed on the Parties under this Agreement.

7.1.5 Review of Promotional Materials in the United States. The

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relevant legal or regulatory personnel of each Party shall have the opportunity to review and comment on all Promotional Materials in the United States prior to use and such comments shall be considered by Joint Marketing Committee in the preparation of such Promotional Materials.

7.1.6 Use of Promotional Materials in the United States. Except as

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provided in Section 7.1.1, neither Party shall produce (other than as concepts for consideration by the other Party), distribute or otherwise use any Promotional Materials in the United States in connection with Co-Promoting the Collaboration Products unless and until such Promotional Materials have been approved in accordance with this Agreement.

7.1.7 Markings of Promotional Materials in the ROW. To the extent

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required by applicable Law, and further to the extent reasonably practicable, all promotional materials used in the ROW will indicate that the Collaboration Products are sold under license from Adolor.

7.1.8 Discontinued Use.

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(a) Promptly after the termination or expiration of the Adolor

Product Promotion Term, GSK shall (a) immediately cease use of all Promotional Materials relating to the Adolor Products in the United States, (b) return, or otherwise dispose of in accordance with instructions from Adolor, all Promotional Materials relating to the Adolor Products in the United States that remain in GSK's or its Affiliates' possession or control, and (c) upon written request by Adolor provide Adolor with a certified statement that

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all such remaining Promotional Materials relating to the Adolor Products in the United States have been returned or otherwise properly disposed of, and that GSK is no longer in possession or control of any such Promotional Materials relating to the Adolor Products in the United States.

(b) Promptly after the termination of the GI Product Promotion

Term, GSK shall (a) immediately cease use of all Promotional Materials relating to the GI Products in the United States, (b) return, or otherwise dispose of in accordance with instructions from Adolor, all Promotional Materials relating to the GI Products in the United States that remain in GSK's or its Affiliates' possession or control, and (c) upon written request by Adolor provide Adolor with a certified statement that all such remaining Promotional Materials relating to the GI Products have been returned or otherwise properly disposed of, and that GSK is no longer in possession or control of any such Promotional Materials relating to the GI Products in the United States.

7.1.9 Discontinued Use of Promotional Materials in the ROW. On a

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Collaboration Product-by-Collaboration Product and Country-by-Country basis in the ROW, in the event this Agreement is terminated prior to expiration of the ROW Term, GSK shall (a) immediately cease use of all promotional materials in such Country in the ROW, (b) return, or otherwise dispose of in accordance with instructions from Adolor, all promotional materials in such Country in the ROW that remain in GSK's or its Affiliates' or sublicensees' possession or control, and (c) upon written request by Adolor provide Adolor with a certified statement that all such remaining promotional materials in such Country in the ROW have been returned or otherwise properly disposed of, and that GSK is no longer in possession or control of any such promotional materials in such Country in the

ROW.

## 7.2 Samples for the United States.

### 7.2.1 Make-Up of Package and Package Inserts of Samples. In the

United States, packaging, package inserts and outserts, Sample labels and labeling shall each contain appropriate reference to Adolor and GSK with equal exposure and prominence as may be permitted under applicable FDA rules and regulations including, without limitation, 21 C.F.R. (S) 201.1(h). The Parties agree to cooperate and use Commercially Reasonable Efforts to secure such approval from the FDA.

### 7.2.2 Shipment, Storage and Allocation of Samples. Reasonable

requirements of Samples for the United States shall be shipped to each Party's or its designee's distribution facility in a timely manner in accordance with the schedule for distribution as outlined in the U.S. Marketing Plan. Each Party shall be responsible for supplying its Sales Representatives in the United States with Samples from such Party's or its designee's distribution facility.

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### 7.2.3 Sampling in the United States. Each Party shall use Samples in

the United States strictly in accordance with the then-current U.S. Marketing Plan and shall distribute Samples in full compliance with all applicable Laws, including the requirements of the Prescription Drug Marketing Act of 1987, as amended (the "PDM Act"). Specifically, the Parties shall establish, maintain and

adhere to written procedures to assure that each Party and its professional representatives comply with all requirements of the PDM Act. Such procedures shall include a requirement that each Party notify the other immediately upon learning that any Samples shipped by to a Party have been lost or have not been received as scheduled. Each Party will maintain records as required by the PDM Act and all other Laws and shall allow representatives of the other Party to inspect such records on request. Each Party shall be responsible for the filing

of any necessary reports to FDA in connection with the PDM Act, and a Party shall provide the other Party in a timely fashion with any necessary information in connection with such reporting under the PDM Act.

#### 7.2.4 Audit Rights in the United States in Relation to Sampling. Upon

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reasonable advance notice to a Party, the other Party shall be entitled, at such Party's expense, to conduct an inspection and audit of the other Party's Sample distribution practices by its Sales Representatives in the United States and any of such Party's owned or controlled facilities where Samples are stored. Such inspection and audit shall be made in accordance with the applicable provisions of the PDM Act and with the provisions of this Agreement.

### ARTICLE 8

#### INFORMATION CONCERNING THE COLLABORATION PRODUCTS

##### 8.1 Statements Consistent with Labeling. Neither Party shall make, nor

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permit its Sales Representatives to make, any promotional statement, representation or warranty, oral or written, concerning Collaboration Products inconsistent with, or contrary to, the approved Collaboration Product labeling or Promotional Materials. In addition, each Party shall insure that its Sales Representatives Detail the Collaboration Products in a fair and balanced manner in the United States and the ROW and consistent with the requirements of the Federal Food, Drug and Cosmetic Act of the United States, as amended, including, but not limited to, the regulations at 21 C.F.R. (S) 202 in the United States.

##### 8.2 Medical Inquiries. Adolor shall identify to GSK the Person or Persons

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to whom GSK and its Affiliates shall refer all medical questions or inquiries from members of the medical and paramedical professions and consumers regarding the Adolor Products in the United States that GSK and its Affiliates cannot readily answer by reference to the Adolor Product literature. GSK shall identify to Adolor the Person or Persons to whom Adolor and its Affiliates shall refer all medical questions or inquiries from members of the medical and paramedical professions and consumers regarding the GI Product in the United States and the Collaboration Products in the ROW that Adolor and its Affiliates cannot readily answer by reference to the GI Product literature or Collaboration Product

literature, as applicable. Each Party shall use Commercially Reasonable Efforts to refer,

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and to cause its Affiliates to refer, all such medical questions or inquiries to such identified Person or Persons.

8.3 Standard Operating Procedures. Within ninety (90) days after the

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Effective Date, the Parties shall develop a set of standard operating procedures for responding promptly to medical questions or inquiries in the United States from members of the medical and paramedical professions and consumers relating to the Collaboration Products. In addition, the Parties will develop processes to train personnel of each Party to respond consistently to such questions or inquiries. For Collaboration Products in the ROW, GSK will follow appropriate standard operating procedures consistent with all applicable Laws.

## ARTICLE 9

### REGULATORY MATTERS

9.1 Communications and Meetings with Governmental Authorities.

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9.1.1 By GSK. Subject to the provisions of the Pharmacovigilance

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Agreement, GSK shall not, without the consent of Adolor, correspond or communicate with any Governmental Authority in the United States concerning the Adolor Products, or otherwise take any action with any Governmental Authority in the United States concerning any Investigational Authorization or Marketing Authorization or permission under which the Adolor Products are sold or any application for the same, except as may be required by Law. Furthermore, GSK shall, promptly upon receipt of any material contact with or communication from any Governmental Authority relating to a Collaboration Product, but in no event more than two (2) Business Days after such receipt or contact, forward a copy or description of the same to Adolor and respond to all reasonable inquiries by Adolor relating thereto. GSK shall notify Adolor of any meeting with a Governmental Authority relating to a Collaboration Product and Adolor may elect one person reasonably acceptable to GSK (such approval not to be unreasonably

withheld, refused, conditioned or delayed) to participate as an observer (at Adolor's cost and expense) in such meeting. If GSK is advised by its counsel that it must communicate with any Governmental Authority, then GSK shall promptly, but in no event more than two (2) Business Days, advise Adolor of the same and provide Adolor in advance with a copy of any proposed written communication with such Governmental Authority and comply with any and all reasonable requests of Adolor concerning any meeting or written or oral communication with such Governmental Authority.

9.1.2 By Adolor. Subject to the provisions of the Pharmacovigilance

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Agreement, Adolor shall not, without the consent of GSK, correspond or communicate with any Governmental Authority in the United States concerning the GI Products, or otherwise take any action with any Governmental Authority in the United States concerning any Marketing Authorization or permission under which the GI Products are sold or any application for the same, except as may be required by Law. Furthermore, Adolor shall, promptly upon receipt of any material contact

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with or communication from any Governmental Authority relating to a Collaboration Product, but in no event more than two (2) Business Days after such receipt or contact, forward a copy or description of the same to GSK and respond to all reasonable inquiries by GSK relating thereto. Adolor shall notify GSK of any meeting with a Governmental Authority relating to a Collaboration Product and GSK may elect one person reasonably acceptable to Adolor (such approval not to be unreasonably withheld, refused, conditioned or delayed) to participate as an observer (at GSK's cost and expense) in such meeting. If Adolor is advised by its counsel that it must communicate with any Governmental Authority, then Adolor shall promptly, but in no event more than two (2) Business Days, advise GSK of the same and provide GSK in advance with a copy of any proposed written communication with such Governmental Authority and comply with any and all reasonable requests of GSK concerning any meeting or written or oral communication with such Governmental Authority.

9.1.3 Notification by Adolor of any Governmental Actions. Adolor

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shall promptly, but in no event more than two (2) Business Days after receipt of any inspections, proposed regulatory actions, investigations or requests by any Governmental Authority with respect to the Adolor Products in the United States, as well as any corrective actions initiated by Adolor with respect thereto, notify GSK in detail with respect thereto and will provide GSK with copies of all material related documentation. GSK shall have the right to participate in all material preparation, internal caucus, and debriefing sessions related to meetings or discussions to the extent practicable, whether in person, by teleconference or otherwise, between Adolor or its agents and any Governmental Authority with respect to the Adolor Products in the United States, and Adolor shall provide GSK with reasonable prior written notice of any such sessions and copies of meeting minutes with respect thereto.

9.1.4 Notification by GSK of any Governmental Actions. GSK shall

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promptly, but in no event more than two (2) Business Days after receipt of any inspections, proposed regulatory actions, investigations or requests by any Governmental Authority with respect to the GI Products in the United States and with respect to the Collaboration Product in ROW, as well as any corrective actions initiated by GSK with respect thereto, notify Adolor in reasonable detail with respect thereto and will provide Adolor with copies of all material related documentation. Adolor shall have the right to participate in all material preparation, internal caucus, and debriefing sessions related to meetings or discussions to the extent practicable, whether in person, by teleconference or otherwise, between GSK or its agents and any Governmental Authority with respect to the GI Products in the United States and with respect to the Collaboration Product in ROW, and GSK shall provide Adolor with reasonable prior written notice of any such sessions and copies of meeting minutes with respect thereto.

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9.2 Filings with Governmental Authorities.

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9.2.1 Adolor Products in the United States. Adolor will be solely

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responsible for and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining Investigational Authorizations and Marketing Authorizations for the Adolor Products in the United States, including without limitation the responsibility for applying for price approvals for the Adolor Products if required. Upon request by Adolor, GSK shall use Commercially Reasonable Efforts to assist Adolor in applying for, obtaining and maintaining such Investigational Authorizations and Marketing Authorizations (including, with respect to price approvals, as requested by Adolor) for the Adolor Products in the United States. Adolor will be the sole owner of any Investigational Authorizations and Marketing Authorizations for the Adolor Products in the United States. Upon receipt of the initial Investigational Authorizations and Marketing Authorization for the Adolor Products in the United States, Adolor shall have exclusive authority and responsibility to and will use Commercially Reasonable Efforts to maintain and seek appropriate revisions of the conditions of each such Investigational Authorization and Marketing Authorization for the Adolor Products, provided any such revisions are not inconsistent with the provisions of this Agreement or the U.S. Marketing Plan. Adolor shall promptly and in accordance with applicable Law provide to GSK copies of any material documents or correspondence received from any Governmental Authority in the United States, but in no event more than two (2) Business Days after such receipt, that pertains to the Adolor Products (including without limitation any minutes from a meeting with respect thereto). In addition, Adolor shall provide GSK with drafts of any material documents or correspondence to be submitted to any Governmental Authority in the United States that pertains to the Adolor Products. Adolor will consult in advance with, and consider in good faith any comments of, GSK with respect to any filings made or other actions taken by Adolor in accordance with the terms of this Section 9.2, including without limitation any such filings or actions with respect to any changes or modification to labeling for or the indications of the Adolor Products.

9.2.2 GI Products in the United States. Subject to Sections 4.2 and

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5.4, GSK will be solely responsible for and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining Investigational



Authorizations and Marketing Authorizations for the GI Products in the United States, including without limitation the responsibility for applying for price approvals for the GI Products if required. Upon request by GSK, Adolor shall use Commercially Reasonable Efforts to assist GSK in applying for, obtaining and maintaining such Investigational Authorizations and Marketing Authorizations (including, with respect to price approvals, as requested by GSK) for the GI Products in the United States. GSK will be the sole owner of any Investigational Authorizations and Marketing Authorizations for the GI Products in the United States. Upon receipt of the initial Investigational Authorization and Marketing Authorization for the GI Products in the United States, GSK shall have exclusive authority and responsibility to and will use Commercially Reasonable Efforts to maintain and

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seek appropriate revisions of the conditions of each such Investigational Authorization and Marketing Authorization for the GI Products, provided any such revisions are not inconsistent with the provisions of this Agreement or the U.S. Marketing Plan. GSK shall promptly and in accordance with applicable Law provide to Adolor copies of any material documents or correspondence received from any Governmental Authority in the United States, but in no event more than two (2) Business Days after such receipt, that pertains to the GI Products (including without limitation any minutes from a meeting with respect thereto). In addition, GSK shall provide Adolor with drafts of any material documents or correspondence to be submitted to any Governmental Authority in the United States that pertains to the GI Products. GSK will consult in advance with, and consider in good faith any comments of, Adolor with respect to any filings made or other actions taken by GSK in accordance with the terms of this Section 9.2, including without limitation any such filings or actions with respect to any changes or modification to labeling for or the indications of the GI Products.

9.2.3 Disputes Concerning Regulatory Matters. All disputes concerning

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regulatory matters shall be resolved by the appropriate committee in accordance with Article 3.

9.3 In the ROW. Subject to Sections 4.2 and 5.4, GSK will be solely

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responsible for and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining Investigational Authorizations and Marketing Authorizations for the Collaboration Products in the ROW, including without limitation the responsibility for applying for price approvals for the Collaboration Products if required. GSK will be the sole owner of any Investigational Authorizations and Marketing Authorizations for the Collaboration Products in the ROW. Upon receipt of the initial Investigational Authorization and Marketing Authorization for the Collaboration Products in the ROW, GSK shall have exclusive authority and responsibility to and will use Commercially Reasonable Efforts to maintain and seek appropriate revisions of the conditions of each such Investigational Authorization and Marketing Authorization for the Collaboration Products, provided any such revisions are not inconsistent with the provisions of this Agreement or the Commercialization of Products in the United States. GSK shall promptly and in accordance with applicable Laws, but in no event more than five (5) Business Days after such receipt, provide to Adolor copies of any material documents or correspondence received from any Governmental Authority in \*\* relating to the Adolor Products (including without limitation any minutes from a meeting with respect thereto). In addition, GSK shall provide Adolor with drafts of any material documents or correspondence to be submitted to any Governmental Authority in a \*\* that pertains to the Adolor Products. GSK will consult in advance with and, subject to the terms of Section 9.1 and the Pharmacovigilance Agreement, and consistent with this Section 9.2, GSK will not file any such material document with any Governmental Authority in a \*\* relating to the Collaboration Products that could have an effect on the Adolor Products in the United States without the prior written consent of Adolor, such consent not to be unreasonably withheld, refused, conditioned or delayed; provided that if Adolor does not respond to GSK within

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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two (2) Business Days after receipt of a copy of such material document, GSK shall be permitted to file such material document without the prior written consent of Adolor.

#### 9.4 Approval of Labeling and Promotional Materials.

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9.4.1 By Adolor. Subject to the provisions of this Article 9, Adolor,  
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in the United States, shall have sole authority and responsibility to seek and/or obtain any necessary Governmental Authority approvals of any label, labeling, package inserts or outserts, monographs and packaging, and Promotional Materials that are approved by the Joint Marketing Committee for use in connection with the Adolor Products, and for determining whether the same requires Governmental Authority approval. Upon request by Adolor, GSK shall use Commercially Reasonable Efforts to assist Adolor in its efforts to seek and obtain such Governmental Authority approvals.

9.4.2 By GSK. Subject to the provisions of this Article 9, GSK, in  
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the United States, shall have sole authority and responsibility to seek and/or obtain any necessary Governmental Authority approvals of any label, labeling, package inserts or outserts, monographs and packaging, and Promotional Materials that are approved by the Joint Marketing Committee for use in connection with the GI Products, and for determining whether the same requires Governmental Authority approval. Upon request by GSK, Adolor shall use Commercially Reasonable Efforts to assist GSK in its efforts to seek and obtain such Governmental Authority approvals.

9.4.3 Committee Approval. Subject to Section 3.1.4(b), no  
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Collaboration Product label, labeling, package inserts or outserts, monographs, packaging or Promotional Materials may be used or distributed by either Party in the United States unless such label, labeling, package inserts or outserts, monographs, packaging or Promotional Materials have been approved in advance by the Joint Marketing Committee or the Joint Steering Committee.

#### 9.5 Regulatory Information.

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9.5.1 Assistance. Subject to the terms of Section 9.1, in the United

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States, each Party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Law applicable to the Collaboration Products, including, but not limited to, Adolor meeting its reporting and other obligations to maintain and update any Marketing Authorizations for the Collaboration Products.

9.5.2 Notice. Each Party shall provide the other Party with notice,

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in a sufficiently timely basis to enable the other Party to comply in all material respects with applicable Laws, of notification or other information which it receives (directly or indirectly) from, any Governmental Authority (and providing, as soon as reasonably possible, copies of any associated written requests) that (i) raises any

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material concerns regarding the safety or efficacy of a Collaboration Product, (ii) indicates or suggests a Claim of a Third Party arising in connection with a Collaboration Product, or (iii) is reasonably likely to lead to a recall or market withdrawal of a Collaboration Product, provided that neither Party shall be obliged to disclose information in breach of any contractual restriction which it could not reasonably have avoided. Information that shall be disclosed pursuant to this Section 9.5.2 shall include, but not be limited to:

- (a) Inspections by a Governmental Authority of manufacturing, distribution or other related facilities concerning a Collaboration Product;
- (b) Inquiries by a Governmental Authority concerning clinical investigation activities (including without limitation inquiries regarding investigators, clinical monitoring organizations and other related parties) with respect to a Collaboration Product;
- (c) Any communication from a Governmental Authority involving the manufacture, sale, promotion or distribution of a Collaboration Product, or any other Governmental Authority reviews or inquiries relating to a any event set forth in this Section 9.5.2;

(d) An initiation of any Governmental Authority investigation, detention, seizure or injunction concerning a Collaboration Product; and

(e) Any other regulatory action (e.g., proposed labeling or other registrational dossier changes and recalls) which would affect a Collaboration Product in any Country.

9.6 Exchange of Drug Safety Information. Within ninety (90) days after the

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Effective Date, the Parties shall enter into the Pharmacovigilance Agreement.

Each Party shall ensure that, in the Development or Commercialization of the Collaboration Products, it and each of its respective Affiliates will record, investigate, summarize, notify, report and review all Adverse Drug Experiences in accordance with Law and the Pharmacovigilance Agreement. Each Party shall require that such Affiliates (i) adhere to all requirements of applicable Laws which relate to the reporting and investigation of Adverse Drug Experiences, and (ii) keep the Parties informed of such events.

9.7 Recalls Or Other Corrective Action.

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9.7.1 In the United States.

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(a) Adolor shall promptly notify GSK of any material actions to be taken by Adolor with respect to any recall or market withdrawal or other corrective action related to the Adolor Products in the United States prior to such action so as to permit GSK a reasonable opportunity to consult with Adolor with respect thereto. Adolor agrees to consider GSK's consultation; provided, however, nothing in this Section is intended to limit Adolor's ability to recall, withdraw or take any other corrective

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action relating to the Adolor Products in the United States. At Adolor's request, GSK shall provide reasonable assistance to Adolor in conducting such recall, market withdrawal or other corrective action in the United States. In accordance with the foregoing, Adolor shall make all decisions with respect to any recall, market withdrawals or any other corrective action related to the Adolor Products in the United States.

(b) GSK shall promptly notify Adolor of any material actions to be taken by GSK with respect to any recall or market withdrawal or other corrective action related to the GI Products in the United States prior to such action so as to permit Adolor a reasonable opportunity to consult with GSK with respect thereto. To the extent Adolor reasonably believes any such action is likely to adversely affect the POI Product in the United States, Adolor shall notify GSK and GSK shall not take any action without the prior written consent of Adolor unless otherwise required by Law. In accordance with the foregoing, GSK shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawals or any other corrective action related to the GI Products in the United States.

(c) Each Party shall, as soon as practicable, notify the other Party of any recall information received by it in sufficient detail to allow the Parties to comply with any and all applicable Laws.

(d) Any documented, direct, out-of-pocket costs incurred (i.e., paid or accrued) by a Party with respect to participating in such recall, market withdrawal or other corrective action in the United States shall be deemed a Marketing Expense of such Party; provided, however, that if such recall, market withdrawal or other corrective action was caused by a Party's negligence, willful misconduct or breach of this Agreement occurring while the Collaboration Product was under such Party's or its distributors or manufacturers' control (e.g., mishandling or adulteration of the Collaboration Product in such Party's or its distributor's or manufacturers' warehouse), such Party shall reimburse the other Party for such costs and they shall not be deemed a Marketing Expense. In no event shall a Party or its Affiliates or sublicensees be deemed a distributor or manufacturer of the other Party under the preceding sentence.

9.7.2 In the ROW. GSK shall promptly notify Adolor of any material

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actions to be taken by GSK with respect to any recall or market withdrawal or other corrective action related the Collaboration Products in the ROW prior to such action to permit Adolor a reasonable opportunity to consult with GSK with respect thereto. To the extent Adolor reasonably believes any such action is likely to adversely affect the POI Product in the United States, Adolor shall

notify GSK and GSK shall not take any action without the prior written consent of Adolor unless otherwise required by Law. All costs and expenses with respect to a recall, market withdrawal or other corrective action in the ROW shall be borne by GSK unless such recall, market withdrawal or other corrective action was due solely to

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the negligence, willful misconduct or breach of this Agreement by Adolor. In accordance with the foregoing, GSK shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawals or any other corrective action related to the Collaboration Products in the ROW.

9.8 Events Affecting Integrity or Reputation. During the Term, the Parties

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shall notify each other immediately of any circumstances of which they are aware and which could impair the integrity and reputation of the Collaboration Products or if a Party is threatened by the unlawful activity of any Third Party in relation to the Collaboration Products, which circumstances shall include, by way of illustration, deliberate tampering with or contamination of the Collaboration Products by any Third Party as a means of extorting payment from the Parties or another Third Party. In any such circumstances, the Parties shall use Commercially Reasonable Efforts to limit any damage to the Parties and/or to the Collaboration Products. The Parties shall promptly call a Joint Steering Committee meeting to discuss and resolve such circumstances.

9.9 Sharing of Regulatory Filings. GSK shall permit Adolor access to and

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grant Adolor the right to reference and use, in association with the Collaboration Products and the Combination Products, all data, regulatory filings and regulatory communications associated with any submissions for Investigational Authorization or Marketing Authorization or other issues associated with any Collaboration Product or GSK Other GI Product that is or would be relevant to Adolor's Development or Commercialization of a Collaboration Product or Combination Product. Adolor shall permit GSK access to and grant GSK the right to reference and use, in association with the Collaboration Products, all data, regulatory filings and regulatory

communications associated with any submissions for Investigational Authorization or Marketing Authorization or other issues associated with any Collaboration Product or, subject to any Third Party Rights, Combination Products, that is or would be relevant to GSK's Development or Commercialization of a Collaboration Product. To the extent that any such data, regulatory filings or regulatory communications are held by a Third Party, then Adolor or GSK, as the case may be, shall endeavor to arrange direct access to the portions of such data, regulatory filings or regulatory communications that are relevant to the activities of the other Party that are contemplated by this Agreement.

## ARTICLE 10

### ORDERS; SUPPLY AND RETURNS

#### 10.1 Orders and Terms of Sale in the United States for Adolor Products.

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Except as otherwise expressly set forth in Section 5.5.2(b) or the distribution services agreement contemplated in Section 6.3.3, Adolor shall have the sole right in the United States to (i) receive, accept and fill orders for the Adolor Products, (ii) control invoicing, order

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processing and collection of accounts receivable for the sales of the Adolor Products and (iii) record the sales of the Adolor Products in its books of account.

#### 10.2 Orders and Terms of Sale in the United States for GI Products. Except

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as otherwise expressly stated in this Agreement, GSK shall have the sole right in the United States to (i) receive, accept and fill orders for the GI Products, (ii) control invoicing, order processing and collection of accounts receivable for the sales of the GI Products and (iii) record the sales of the GI Products in its books of account.

#### 10.3 Orders and Terms of Sale in the ROW. Except as otherwise expressly

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stated in this Agreement, GSK shall have the sole right in the ROW to (i) receive, accept and fill orders for the Collaboration Products, (ii) control invoicing, order processing and collection of accounts receivable for the



Collaboration Products sales, (iii) record the Collaboration Products sales in its books of account, and (iv) establish and modify the commercial terms and conditions with respect to the sale and distribution of the Collaboration Products, including without limitation matters such as the price at which the Collaboration Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed.

10.4 Misdirected Orders. If, for any reason, GSK receives orders for the

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Adolor Products in the United States, GSK shall forward such orders to Adolor (or if directed by Adolor to Adolor's wholesalers) as soon as practicable. If, for any reason, Adolor receives orders for the GI Products in the United States or for the Collaboration Products in the ROW, Adolor shall forward such orders to GSK (or if directed by GSK to GSK's wholesalers) as soon as practicable.

10.5 Product Returns.

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10.5.1 Adolor Product Returns. If any quantities of an Adolor Product

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are returned to GSK in the United States, GSK shall immediately notify Adolor and ship them to the facility designated by Adolor, with any reasonable or authorized shipping or other documented direct cost to be paid by Adolor. GSK, at its option, may advise the customer who made the return that the Adolor Product should have been returned to Adolor, but shall take no other steps in respect of any return without the consent of Adolor, such consent not to be unreasonably withheld, refused, conditioned or delayed. At Adolor's request, GSK shall destroy the Adolor Product, the cost of such destruction to be deemed a Marketing Expense; provided, however, that in the event the Adolor Product is returned as a result of Adolor's breach of this Agreement, or otherwise as a result of Adolor's negligence, than any costs associated with such destruction shall be the sole responsibility of Adolor.

10.5.2 GI Product Returns. If any quantities of an GI Product are

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returned to Adolor in the United States, Adolor shall immediately notify GSK and ship them to the facility designated by GSK, with any reasonable or authorized shipping or other documented direct cost to be paid by GSK. Adolor, at its

option, may advise the customer who made the return that the GI Product should have been returned to GSK, but shall take no other steps in respect of any return without the consent of GSK, such consent not to be unreasonably withheld, refused, conditioned or delayed. At GSK's request, Adolor shall destroy the GI Product, the cost of such destruction to be deemed a Marketing Expense; provided, however, that in the event the GI Product is returned as a result of GSK's breach of this Agreement, or

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otherwise as a result of GSK's negligence, than any costs associated with such destruction shall be the sole responsibility of GSK.

#### 10.6 Supply of API Compound and Collaboration Product for Development of

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Collaboration Products.  
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##### 10.6.1 Supply of API Compound for Development. Subject to the terms

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and conditions of this Agreement, Adolor shall be responsible to supply, or to obtain supply, for worldwide requirements of API Compound to enable the Parties to fulfill their obligations to Develop Collaboration Products under this Agreement. API Compound requirements for Development activities shall be set forth in the relevant U.S. Development Plans and ROW Development Plans and shall be periodically updated by the Joint Supply Committee in coordination with the Joint Development Committee and the Joint Steering Committee.

##### 10.6.2 Supply of Formulated Collaboration Products for Development.

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Subject to the terms and conditions of this Agreement, Adolor shall be responsible to supply, or to obtain supply, for GSK's worldwide requirements of formulated GI Products and GSK's ROW requirements of formulated Adolor Products to enable GSK to fulfill its obligations to Develop Collaboration Products until such time as GSK can supply such formulated Collaboration Products alone or with Third Parties. Formulated Collaboration Product requirements for Development activities shall be set forth in the relevant U.S. Development Plans and ROW Development Plans and shall be periodically updated by the Joint Supply

Committee in coordination with the Joint Development Committee and the Joint Steering Committee.

10.6.3 Cost of Supply. Adolor shall supply such API Compound and such

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formulated Collaboration Products to GSK at Adolor's Cost of Goods therefor and GSK shall be responsible for shipping, insurance and other related expenses. For the time period from the Effective Date through \*\*, the Cost of Goods for API Compound shall \*\*, unless otherwise mutually agreed between the Parties.

Thereafter, Adolor will use Commercially Reasonable Efforts to provide a Cost of Goods for API Compound \*\*, unless otherwise mutually agreed between the Parties, to be adjusted for inflation commencing with the Calendar Year beginning January 1, 2004, using the Producer Price Index as published by the Bureau of Labor Statistics of the U.S. Department of Labor; provided Adolor will use Commercially Reasonable Efforts to decrease the cost of such API Compound and formulated Collaboration Products. GSK shall pay for such API Compound in advance to the extent that Adolor is required to make payments in advance to its Product Supplier.

10.6.4 Clinical Supply Agreement. Within \*\* (\*\*) days after the

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Effective Date, the Parties shall negotiate and agree in good faith a supply agreement relating to supply to GSK of its worldwide requirements of API Compound and its short-term requirements of formulated Collaboration Products for Development activities, addressing the standard terms of supply set forth in  
\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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Section 10.11 (the "Standard Terms") and relevant other terms relating to

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specifications and quantities required. The Parties acknowledge that Product Suppliers engaged by Adolor will carry out such manufacture and supply on Adolor's behalf. Upon receipt of any API Compound supplied under such supply agreement, GSK shall have thirty (30) days to perform the Testing Protocol to

determine if such API Compound conforms to the specifications and GSK shall promptly notify Adolor of any API Compound that does not conform to the specifications. On an interim basis pending effectiveness of such a supply agreement, Adolor shall use Commercially Reasonable Efforts to supply GSK with GSK's supply requirements of API Compound and formulated Collaboration Products for Development activities under this Agreement in the following amounts and timeframes (a) \*\* grams as capsules in the \*\* Calendar Quarter of Calendar Year 200\*\*, (b) \*\* grams as capsules at the end of \*\* Calendar Quarter of Calendar Year 200\*\*, (c) \*\* grams of API Compound in the \*\* Calendar Quarter of Calendar Year 200\*\*, (d) \*\* grams of API Compound in the \*\* Calendar Quarter of Calendar Year 200\*\*, and (e) \*\* kilograms at times to be agreed upon by the Joint Supply Committee; provided, however, that GSK shall provide in conjunction with such supply requirements more detail to Adolor in writing, sufficiently in advance of the date needed and with sufficient regard to the lead times involved to enable Adolor to procure such supply; provided, further, that such request from GSK shall be subject to the condition that the requirements of API Compound and formulated Collaboration Products for use in POI Products for Development and Commercialization in the United States shall have first priority.

#### 10.7 Supply of API Compound for Commercialization of Collaboration

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Products.

##### ----- 10.7.1 Commercial Requirements for API Compound. Subject to the terms

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and conditions of this Agreement, Adolor shall be responsible to supply, or to obtain supply, of API Compound to enable the Parties to fulfill their obligations to Commercialize Collaboration Products under this Agreement. Such API Compound shall be supplied in accordance with the principles set out in the Standard Terms and relevant other terms relating to specifications and quantities required. A forecast for API Compound requirements for Commercialization of the Collaboration Products shall be prepared and periodically updated by the Joint Supply Committee and coordinated with the applicable U.S. Marketing Plans for Collaboration Products through the Joint Marketing Committee and through the Joint Steering Committee for

Commercialization in the ROW.

10.7.2 Cost of Supply. Adolor shall supply such API Compound to GSK at

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\*\* and GSK shall be responsible for shipping, insurance and other related expenses. Adolor will use Commercially Reasonable Efforts to provide a Cost of Goods for API Compound not to \*\*, unless otherwise mutually agreed between the Parties, to be adjusted for inflation commencing with the Calendar Year beginning January 1, 200\*\*, using the Producer Price Index as published by the Bureau of Labor Statistics of the U.S. Department of Labor; provided Adolor will use Commercially Reasonable Efforts

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to decrease the cost of such API Compound. GSK shall pay for such API Compound in advance to the extent that Adolor is required to make payments in advance to its Product Supplier.

10.7.3 Supply Agreement. Within one hundred eighty (180) days after

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the Effective Date, the Parties shall negotiate and agree in good faith a supply agreement relating to supply to GSK of its worldwide commercial requirements of API Compound incorporating the Standard Terms and relevant other terms relating to specifications and quantities required. The Parties acknowledge that Product Suppliers engaged by Adolor will carry out such manufacture and supply on Adolor's behalf. Upon receipt of such API Compound, GSK shall have thirty (30) days to perform the Testing Protocol to determine if such API Compound conforms to the specifications and GSK shall promptly notify Adolor of any API Compound that does not conform to the specifications.

10.7.4 Right of First Negotiation. Subject to Adolor's existing

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obligations to its Product Suppliers, GSK shall have a right of first negotiation to become an alternative or primary source of supply of API Compound for Commercialization of all Collaboration Products, at GSK's Cost of Goods

therefor, which shall not be greater than the applicable Product Supplier's Cost of Goods, and Adolor shall consider any such proposal by GSK in good faith. The Parties shall enter into a separate supply agreement if, in accordance with the foregoing, GSK is chosen to become an alternative or primary Product Supplier of API Compound; provided, however, that GSK's Cost of Goods for API Compound shall in no event exceed the cost of API Compound as supplied, or as could be supplied by a Third Party, as measured at the request of Adolor and no more frequently than once per Calendar Year. In the event that GSK is established as a Product Supplier, GSK shall be responsible for all costs and expenses related to any necessary transfer of technology.

#### 10.8 Supply of Collaboration Products for Commercialization.

##### 10.8.1 Supply of Adolor Products in the United States. Subject to the

terms and conditions of this Agreement, Adolor shall be responsible to supply, or to obtain supply, of commercial requirements of formulated, packaged and labeled Adolor Products for the United States during the Adolor Product Promotion Term. Such formulated, packaged and labeled Adolor Products for the United States shall be supplied in accordance with the principles set out in the Standard Terms and relevant other terms relating to specifications and quantities required. The Joint Marketing Committee shall prepare and update quarterly a rolling three (3) year forecast of the demand for the Adolor Products by Calendar Quarter for the United States, which will be provided to and monitored by the Joint Supply Committee. Notwithstanding the foregoing, the Parties may determine that some or all of any aspect of secondary manufacturing activity, including but not limited to formulation manufacturing, labeling and packaging, of the Adolor Products may be performed by GSK on terms to be determined by the Parties.

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##### 10.8.2 Supply of GI Products in the United States. Subject to the

terms and conditions of this Agreement, GSK shall be responsible to supply, or to obtain supply, of the Parties' commercial requirements of formulated,

packaged and labeled GI Products for the United States during the GI Product Promotion Term. Such formulated, packaged and labeled GI Products for the United States shall be manufactured and supplied in accordance with the principles set out in the Standard Terms and relevant other terms relating to specifications and quantities required; provided, however, that GSK's Cost of Goods for formulated, packaged and labeled GI Products for the United States shall in no event exceed the cost of formulated, packaged and labeled GI Products as supplied, or as could be supplied by a Third Party, as measured at the request of Adolor and no more frequently than once per Calendar Year. The Joint Marketing Committee shall prepare and update quarterly a rolling \*\* (\*\*) year forecast of the demand for the GI Products by Calendar Quarter for the United States, which will be provided to and monitored by the Joint Supply Committee.

#### 10.8.3 Supply of Collaboration Products for the ROW. Subject to the

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terms and conditions of this Agreement, GSK shall be responsible to supply, or to obtain supply, of the commercial requirements of formulated, packaged and labeled Collaboration Products for the ROW during the ROW Term. Such formulated, packaged and labeled Collaboration Products for the ROW shall be manufactured and supplied in accordance with all applicable Laws and current Good Manufacturing Practices. GSK shall be solely responsible for secondary manufacture, packaging and labeling of the GI Products for Commercialization in the United States and for Collaboration Products in the ROW. In order to give effect to the foregoing, Adolor shall be responsible to supply, or to obtain supply, for GSK's requirements of API Compound pursuant to Section 10.7.

#### 10.9 Shortages. Adolor shall give GSK written notice as soon as reasonably

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practicable if Adolor becomes aware that its Product Suppliers will not be able to substantially satisfy the Parties' requirements for API Compound, and the Parties shall give each other written notice as soon as reasonably practicable if either Party becomes aware that its Product Suppliers will not be able to substantially satisfy the Parties' requirements for formulated Collaboration Products, for whatever reason. In the event that there is a failure to substantially satisfy the Parties' requirements of API Compound or formulated Collaboration Product, provided that such requirements cannot be satisfied by

the Parties' inventories of API Compound or formulated Collaboration Product, and additionally provided that such failure will or does result in an interruption of supply of Collaboration Products to the commercial market, then GSK and Adolor will immediately work together, in good faith, to identify an appropriate alternative source of API Compound or formulated Collaboration Products supply, provided that:

10.9.1 Efforts to Supply Requirements. Adolor shall use its

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Commercially Reasonable Efforts to supply the Parties' requirements for API Compound in accordance with Section 3.4.2(c), and the Parties shall use their Commercially Reasonable Efforts to supply the Parties' requirements for formulated Collaboration Product; and

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10.9.2 Manufacturing by GSK During Shortage. GSK shall be entitled to

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assume responsibility for supply and manufacture of API Compound or formulated Collaboration Product for such period as the shortage may exist to address and satisfy the Parties' requirements for such API Compound or formulated Collaboration Product in the interim and, in order to facilitate same, Adolor shall grant GSK the licenses set forth in Section 2.1.6 and, upon request, effect any transfer of applicable data and information immediately forthwith. The foregoing right of GSK to assume responsibility for supply and manufacture of API Compound or formulated Collaboration Product shall also apply in the event that Adolor's supply of API Compound or such Collaboration Product repeatedly does not meet the respective specifications therefor.

10.10 Product Suppliers. In order to fulfill their respective obligations

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under this Article 10, and without prejudice to the terms and conditions of this Article 10, Adolor and GSK shall each be responsible for: (a) entering into appropriate supply agreements with Product Suppliers; (b) transferring



technology to such Product Suppliers; (c) where such Product Suppliers have not already been appointed as of the Effective Date, obtaining approval from the other Party, such approval not to be unreasonably withheld, refused, conditioned or delayed and, for the avoidance of doubt, this requirement for consent shall apply to the appointment of all Product Suppliers under or in connection with this Agreement except Product Suppliers appointed by GSK in the ROW; and (d) obtaining any necessary regulatory approval for the use of such Product Suppliers. Adolor shall make payments to Product Suppliers under its control for Adolor Products for sale and distribution in the United States. GSK shall make payments to Product Suppliers under its control for GI Products for sale and distribution in the United States and for Collaboration Products for sale and distribution in the ROW.

#### 10.11 Standard Terms of Supply.

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##### 10.11.1 Product Supplier Representations.\*\*

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##### 10.11.2 Manufacturing Regulatory Matters. \*\*

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10.11.3 Continuous Improvement. Both Parties agree to use

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Commercially Reasonable Efforts to continuously improve its performance and its Product Suppliers' performance, including, but not limited to, cost of Collaboration Products and API Compound, yield and delivery timing. The Parties shall agree on targets to measure such performance improvements.

10.11.4 Inventories. Both Parties, and their respective Product

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Suppliers, shall maintain an inventory of API Compound and Collaboration Products in accordance with their normal practices and so as to ensure fulfillment of their respective supply obligations herein.

## ARTICLE 11

### GSK PRODUCT

11.1 GSK Product Right and License. Subject to the terms of this

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Agreement, GSK grants to Adolor, and Adolor accepts, the exclusive (except as to GSK and its Affiliates) right, under the Patent Rights and Know-How of GSK and under any copyrights or trademarks owned or controlled by GSK, to detail and co-promote, or if appropriate, and the Parties mutually agree, to sell, through itself or its Affiliates or subcontractors, \*\* prescription pharmaceutical products of GSK that are, at the time of being proposed to Adolor, either being marketed in the United States or in development for commercialization in the United States and which shall be selected pursuant to Section 11.2 (the "GSK --- Products"). -----

11.2 Adolor Selection Process and Timeframe.

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11.3 GSK Product Agreement. \*\*

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11.4 No Selected GSK Product. \*\*

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## ARTICLE 12

### Confidential Information

12.1 Confidential Information. Each of GSK and Adolor shall keep all

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Confidential Information received from the other Party with the same degree of care it maintains the confidentiality of its own Confidential Information.

Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its agents who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement. A Receiving Party shall advise any agent who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure that all such agents comply with such obligations as if they had been a Party hereto. Upon termination of this Agreement, the Receiving Party shall use Commercially Reasonable Efforts to return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the Receiving Party's or its agents' possession, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 12.

Notwithstanding anything to the contrary in this Agreement, the Receiving Party

shall have the right to disclose any Confidential Information provided hereunder if, in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is necessary to comply with the terms of this Agreement, or the requirements of any Law. Where possible, the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make such disclosure of Confidential Information pursuant to the provision of the preceding sentence sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action the Disclosing Party may deem to be appropriate to protect the confidentiality of the information.

12.2 Permitted Disclosure and Use. Notwithstanding Section 12.1, a Party

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may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) obtain Marketing Authorization of a Collaboration Product; (b) enforce the provisions of this Agreement; or (c) comply with Laws. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 12.2, such Party shall give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information.

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12.3 Publications. Subject to any Third Party rights existing as of the

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Effective Date, each Party shall submit to the Joint Development Committee or Joint Marketing Committee, as applicable (hereinafter referred to as the "Applicable Committee") for review and approval all proposed academic,

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scientific and medical publications and public presentations relating to a Collaboration Product or any research or Development activities under this Agreement for review in connection with preservation of Patent Rights, and trade secrets and/or to determine whether Confidential Information should be modified

or deleted from the proposed publication or public presentation. Written copies of such proposed publications and presentations shall be submitted to the Applicable Committee no later than sixty (60) days before submission for publication or presentation and the Applicable Committee shall provide its comments with respect to such publications and presentations within ten (10) Business Days of its receipt of such written copy. The review period may be extended for an additional thirty (30) days if a representative of the non-publishing Party on the Applicable Committee can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended. The Parties will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publications relating to the Collaboration Products or any research or Development activities under this Agreement.

12.4 Public Announcements. Except as may be expressly permitted under

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Section 12.3 or required by applicable Laws, neither Party will make any public announcement of any information regarding this Agreement, the Collaboration Products or any research or Development activities under this Agreement without the prior written approval of the other Party. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party.

12.5 Confidentiality of this Agreement. The terms of this Agreement shall

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be Confidential Information of each Party and, as such, shall be subject to the provisions of this Article 12.

12.6 Survival. The obligations and prohibitions contained in this Article

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12 shall survive the expiration or termination of this Agreement for a period of ten (10) years.

## ARTICLE 13

### REPRESENTATIONS AND WARRANTIES; COVENANTS

13.1 Mutual Representations and Warranties. Adolor and GSK each represents

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and warrants to the other as of the Effective Date that:

13.1.1 Such Party (a) is a company duly organized, validly existing,  
and in good standing under the Laws of its incorporation; (b) is duly qualified  
as a corporation and in good standing under the Laws of each jurisdiction where  
its ownership or lease of property or the conduct of its business requires such  
qualification, where

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the failure to be so qualified would have a material adverse effect on its  
financial condition or its ability to perform its obligations hereunder; (c) has  
the requisite corporate power and authority and the legal right to conduct its  
business as now conducted and hereafter contemplated to be conducted; (d) has or  
will obtain all necessary licenses, permits, consents, or approvals from or by,  
and has made or will make all necessary notices to, all Governmental Authorities  
having jurisdiction over such Party, to the extent required for the ownership  
and operation of its business, where the failure to obtain such licenses,  
permits, consents or approvals, or to make such notices, would have a material  
adverse effect on its financial condition or its ability to perform its  
obligations hereunder; and (e) is in compliance with its charter documents;

13.1.2 The execution, delivery and performance of this Agreement by  
such Party and all instruments and documents to be delivered by such Party  
hereunder (a) are within the corporate power of such Party; (b) have been duly  
authorized by all necessary or proper corporate action; (c) do not conflict with  
any provision of the charter documents of such Party; (d) will not, to the best  
of such Party's knowledge, violate any law or regulation or any order or decree  
of any court of governmental instrumentality; (e) will not violate or conflict  
with any terms of any indenture, mortgage, deed of trust, lease, agreement, or  
other instrument to which such Party is a party, or by which such Party or any  
of its property is bound, which violation would have a material adverse effect  
on its financial condition or on its ability to perform its obligations  
hereunder;

13.1.3 This Agreement has been duly executed and delivered by such

Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies; and

13.1.4 All of its employees, officers, and consultants have executed agreements or have existing obligations under law requiring assignment to such Party of all Inventions made by such individuals during the course of and as the result of their association with such Party, and obligating such individuals to maintain as confidential such Party's Confidential Information, as well as the Confidential Information of Persons doing business with such Party that such individuals may receive during the course of and as the result of their association with such Party, to the extent required to support such Party's obligations under this Agreement.

13.2 Additional GSK Representations and Warranties. GSK further represents,

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warrants and covenants to Adolor that:

13.2.1 It has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of the Compound and the Collaboration Products and has solely relied on such analysis and evaluations in deciding to enter into this Agreement;

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13.2.2 Neither GSK nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any Person obtaining any interest in, or that would give to any Person any right to assert any claim in or with respect to, any of GSK's rights under this Agreement;

13.2.3 GSK shall retain ownership or control of the right to permit Adolor to promote or detail any GSK Product;

13.2.4 There is no claim or demand of any person or entity pertaining to, or any proceeding which is pending or, to the knowledge of GSK, threatened, that challenges the rights of Adolor in respect of any GSK Know-How or GSK Patents, or that claims that any default exists under any license with respect

to any GSK Know-How or GSK Patents to which GSK is a party, except where such claim, demand or proceeding would not materially and adversely affect the ability of GSK to carry out its obligations under this Agreement;

13.2.5 As of the Effective Date, GSK and its Affiliates beneficially own \*\*, in addition to such other shares which may be held as trust assets of pension plan trusts maintained by GSK and its Affiliates and managed by Third Party investment managers; and

13.2.6 Pursuant to the Hart Scott Rodino Antitrust Improvements Act of 1976 (the "HSR Act"), GSK has made the good faith determination that this

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transaction does not satisfy the size of the transaction test as defined under the HSR Act, and therefore, no filing is required under the HSR Act for this transaction.

13.3 Additional Adolor Representations and Warranties. Adolor further

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represents and warrants to GSK as of the Effective Date that:

13.3.1 Adolor has not received notice from any Third Party of a claim that an issued patent of such Third Party in the United States or the ROW would be infringed by the manufacture, distribution, marketing or sale of the Collaboration Products under this Agreement;

13.3.2 To Adolor's knowledge, the Adolor Patents are not subject anywhere in the United States or the ROW to any pending or any threatened, re-examination, opposition, interference or litigation proceedings and Adolor has requested and received confirmation of the same from Lilly;

13.3.3 Adolor has not received notice from any Third Party of a claim asserting the invalidity, misuse, unregistrability or unenforceability of any of the Adolor Patents, or challenging its right to use or ownership of any of the Adolor Patents or the Adolor Know-How, or making any adverse claim of ownership thereof;

13.3.4 Adolor has not received notice from any Third Party that any trade secrets or other intellectual property rights of such Third Party in the United States or the ROW would be misappropriated by the development and reduction to practice of the Adolor Patents and Adolor Know-How;

\*\* = Certain information on this page has been omitted and filed separately with



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13.3.5 Adolor has, up to and including the Effective Date, endeavored in good faith to furnish GSK with all material information requested by GSK concerning the quality, toxicity, safety and/or efficacy concerns that may materially impair the utility and/or safety of the API Compound or Collaboration Products;

13.3.6 Pursuant to that certain License Agreement between Lilly and Roberts Laboratories Inc. dated November 5, 1996 (the "Lilly Agreement") as

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assigned to Adolor by Roberts Laboratories Inc. pursuant to that certain Option and License Agreement dated June 10, 1998, Adolor's licensor, \*\*; and

13.3.7 To Adolor's knowledge, the Lilly Agreement is valid, binding and enforceable in accordance with its respective terms and Adolor has not received any written notice of any material and continuing defaults, breaches or violations under the Lilly Agreement.

13.4 Covenants.

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13.4.1 Each Party hereby covenants and agrees during the Term that it shall carry out the Commercialization of the Collaboration Products and its other obligations or activities hereunder in accordance with (i) the terms of this Agreement and (ii) all applicable Laws.

13.4.2 Each Party hereby covenants and agrees during the Term that it will not enter into any agreement with a Third Party or undertake other activities or commitments, including any such agreement or any such activities or commitments related to any Combination Product, which would have a material adverse effect on (i) its ability to perform all of the obligations undertaken by it and/or (ii) any of the rights granted to the other Party hereunder and/or (iii) the commercial value of any of the Collaboration Products being Developed and/or Commercialized under this Agreement. The Parties acknowledge that this Section 13.4.2 shall not prevent Adolor from entering into an agreement with a Third Party relating to a Combination Product. For purposes of clarity, it is

understood that any Collaboration Product which has been terminated in accordance with this Agreement shall not be subject to the provisions of this Section 13.4.2.

13.4.3 Adolor hereby covenants and agrees during the Term that it shall not knowingly and voluntarily take any action or refrain from taking any action so as to give Lilly cause to terminate the Lilly Agreement.

13.5 Disclaimer of Warranty. Nothing in this Agreement shall be construed

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as a warranty or representation by either Party (i) that any Collaboration Product made, used, sold or otherwise disposed of under this Agreement is or will be free from infringement of patents, copyrights, trademarks, industrial design or other intellectual property rights of

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any Third Party, (ii) regarding the effectiveness, value, safety, non toxicity, patentability, or non-infringement of any patent technology, the Collaboration Products or any information or results provided by either Party pursuant to this Agreement or (iii) that any Collaboration Product will obtain Marketing Authorization or appropriate pricing approval. Each Party explicitly accepts all of the same as experimental and for development purposes, and without any express or implied warranty from the other Party. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

#### ARTICLE 14

##### INDEMNIFICATION

14.1 Indemnification by GSK. Subject to Sections 2.4.8, 14.5 and 15.2, GSK

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shall defend, indemnify and hold harmless Adolor and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the

extent arising out of (a) GSK's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by GSK of any of its representations, warranties, covenants or agreements under this Agreement, or \*\*.

14.2 Indemnification by Adolor. Subject to Sections 2.4.8, 14.5 and 15.2,

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Adolor shall defend, indemnify and hold harmless GSK and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of (a) Adolor's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by Adolor of any of its representations, warranties, covenants or agreements under this Agreement, \*\*.

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14.3 Procedure for Indemnification.

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14.3.1 Notice. Each Party will notify promptly the other if it

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becomes aware of a Claim (actual or potential) by any Third Party (other than any Product Liability Claim provided for under Section 14.5) (a "Third Party

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Claim") for which indemnification may be sought by that Party and will give such

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information with respect thereto as the other Party shall reasonably request. If any proceeding (including any governmental investigation) is instituted involving any Party for which such Party may seek an indemnity under Section 14.1 or 14.2, as the case may be (the "Indemnified Party"), the Indemnified

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Party shall not make any admission or statement concerning such Third Party Claim, but shall promptly notify the other Party (the "Indemnifying Party")

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orally and in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims that are the subject matter of such proceeding. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party or any failure by such Party to notify the Indemnifying Party of the claim materially prejudices the defense of such claim.

14.3.2 Defense of Claim. If the Indemnifying Party elects to defend

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or, if local procedural rules or laws do not permit the same, elects to control the defense of a Third Party Claim, it shall be entitled to do so provided it gives notice to the Indemnified Party of its intention to do so within forty-five (45) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the "Litigation Condition"); provided, that the Indemnifying Party expressly agrees

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the Indemnifying Party shall be responsible for satisfying and discharging any award made to the Third Party as a result of such proceedings or settlement amount agreed with the Third Party in respect of the Third Party Claim without prejudice to any provision in this Agreement or right at law which will allow the Indemnifying Party subsequently to recover any amount from the Indemnified Party to the extent the liability under such settlement or award was attributable to the Indemnified Party. Subject to compliance with the Litigation Condition, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any claim for which it is seeking indemnification without the prior consent of the Indemnifying Party which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such

claim that is being managed and/or controlled by the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of any pending or threatened proceeding in which

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the Indemnified Party is, or based on the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding. If the Litigation Condition is not met, then neither Party shall have the right to control the defense of such Third Party Claim and the Parties shall cooperate in and be consulted on the material aspects of such defense at the each Party's own expense; provided that if the Indemnifying Party does not satisfy the Litigation Condition, the Indemnifying Party may at any subsequent time during the pendency of the relevant Third Party Claim irrevocably elect, if permitted by local procedural rules or laws, to defend and/or to control the defense of the relevant Third Party Claim so long as the Indemnifying Party also agrees to pay the reasonable fees and costs incurred by the Indemnified Party in relation to the defense of such Third Party Claim from the inception of the Third Party Claim until the date the Indemnifying Party assumes the defense or control thereof.

#### 14.4 Assumption of Defense. Notwithstanding anything to the contrary

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contained herein, an Indemnified Party shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnified Party, upon written notice to the Indemnifying Party pursuant to this Section 14.4, in which case the Indemnifying Party shall be relieved of liability under Section 14.1 or 14.2, as applicable, solely for such Third Party Claim and related Losses.

#### 14.5 Product Liability Claims in the United States.

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14.5.1 Except for such Claims for which GSK is obligated to indemnify Adolor under Section 14.1 or Adolor is obligated to indemnify GSK under Section 14.2, each of Adolor and GSK shall be responsible for Losses \*\*. All Product

Liability Claims shall be shared in proportion to \*\*. Notwithstanding the foregoing, Adolor shall not be responsible for any Losses arising out of or resulting from Product Liability Claims in relation to Collaboration Product for which it does not receive a percentage of the Adolor Product Marketing Contribution or a percentage of the GI Product Marketing Contribution unless such Loss is related to a Claim under Section 14.2(a) or 14.2(b).

14.5.2 Each Party shall give the other prompt written notice of any Product Liability Claim (actual or potential), but the omission of such notice shall not relieve either Party from its obligations under this Section 14.5, except to the extent the other Party can establish actual prejudice and direct damages as a result thereof. \*\*

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14.5.3 The Party assuming the lead role shall consult with the other Party on all material aspects of, and shall obtain the prior written consent of the other Party (such consent not to be unreasonably withheld, refused, conditioned or delayed) in respect of any material decisions to be taken with regard to, the defense, including without limitation settlement of such Product Liability Claim, and the other Party shall have a full opportunity to participate in decision-making process with respect to the strategy of such defense, and the Parties shall cooperate fully with each other in connection therewith. The other Party shall also have the right to participate in the defense of any Product Liability Claim utilizing attorneys of its choice, at its own expense. In furtherance of the Parties' cooperation, the Party assuming the lead role will consult with the other Party regarding strategic decisions, including without limitation the retention of counsel and defense of each Product Liability Claim. The Party assuming the lead role will otherwise keep the other Party fully informed of the status and progress of the defense and any settlement discussions concerning the Product Liability Claim.

14.6 Insurance. Immediately upon First Commercial Sale, during the Term

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and for a period of \*\* (\*\*) years after the termination or expiration of this Agreement, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, respectively, which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party. Such product liability insurance or self-insured arrangements shall insure against all liability, including without limitation personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Collaboration Products. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

14.7 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO

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THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER THIS ARTICLE 14 OR INFRINGEMENT CLAIMS UNDER \*\*.

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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## ARTICLE 15

### PATENT INFRINGEMENT

#### 15.1 Prosecution and Maintenance of Patents.

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##### 15.1.1 Prosecution and Maintenance of Adolor Patents. Adolor shall

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have the exclusive right and the obligation to (subject to Adolor's election not to file, prosecute, or maintain pursuant to Section 15.1.4) or to cause its

licensors to, prepare, file, prosecute in a diligent manner (including without limitation by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees, and other such fees and costs required under applicable Laws) and extend all Adolor Patents and related applications. Adolor shall consult with GSK prior to abandoning any Adolor Patents or related applications that are material to the matters contemplated in this Agreement. Adolor shall regularly advise GSK of the status of all pending applications, including with respect to any hearings or other proceedings before any Governmental Authority, and, at GSK's request, shall provide GSK with copies of all documentation concerning such applications, including all correspondence to and from any Governmental Authority. Adolor shall solicit GSK's advice and review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and Adolor shall take into account GSK's reasonable comments related thereto.

#### 15.1.2 Prosecution and Maintenance of Patents Covering Joint

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Inventions.  
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(a) For Patents covering Joint Inventions, the Parties shall agree, without prejudice to ownership, which Party shall have the right to prepare and file a priority patent application, and prosecute such application(s) and maintain any patents derived therefrom, with the Parties equally sharing the reasonable out-of-pocket costs for the preparation, filing, prosecution and maintenance of such priority patent application. Should the agreed upon Party elect not to prepare and/or file any such priority patent application, it shall (i) provide the other Party with written notice as soon as reasonably possible after making such election but in any event no later than sixty (60) days before the other Party would be faced with a possible loss of rights, (ii) give the other Party the right, at the other Party's discretion and sole expense, to prepare and file the priority application(s), and (iii) offer reasonable assistance in connection with such preparation and filing at no cost to the other Party except for reimbursement of reasonable out-of-pocket expenses incurred by the agreed upon Party in rendering such assistance. The other Party,



at its discretion and cost, shall prosecute such application(s) and maintain any patents derived therefrom.

(b) Within nine (9) months after the filing date of a priority application directed to an Invention, the Party filing the priority application shall request that the other Party identify those non-priority ("foreign")

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Countries in which the other Party desires that the Party filing the priority application file corresponding patent applications. Within thirty (30) days after receipt by the other Party of such request from the Party filing the priority application, the other Party shall provide to the Party filing the priority application a written list of such foreign countries in which the other Party wishes to effect corresponding foreign patent applications filings. Thereafter, within twelve (12) months after the filing date of the priority application, the Party filing the priority application shall effect such corresponding foreign filings in the countries selected by the other Party (the filing in such foreign Country being hereinafter referred to as a "Designated

Foreign Filing"). As to each Designated Foreign Filing, GSK shall bear the costs

for the filing and prosecutions of such Designated Foreign Filing. If GSK does not request that an application be filed in a given foreign Country, and Adolor nonetheless effects the filing of a patent application in this given Country, then the costs for such filing and for maintaining such foreign application and any patent issuing thereon shall be borne solely by Adolor. Should the Party filing the priority application not agree to file or cause to be filed a Designated Foreign Filing, the other Party will have the right to effect such Designated Foreign Filing in its name at its own cost.

(c) Should the filing Party pursuant to Section 15.1.2(a) or 15.1.2(b) no longer wish to prosecute and/or maintain any patent application or patent resulting from such application, the filing Party shall (i) provide the non-filing Party with written notice of its wish no later than sixty (60) days before the patent or patent applications would otherwise become abandoned, (ii) give the non-filing Party the right, at the non-filing Party's election and sole

expense, to prosecute and/or maintain such patent or patent application, and

(iii) offer reasonable assistance to the non-filing Party in connection with such prosecution and/or maintenance at not cost to the non-filing Party except for reimbursement of the filing Party's reasonable out-of-pocket expenses incurred by the filing Party in rendering such assistance.

(d) Should the non-filing Party pursuant to Section 15.1.2(c) not wish to incur its share of preparation, filing, prosecution and/or maintenance costs for a patent application filed pursuant to Section 15.1.2(a) or 15.1.2(b) or patents derived therefrom, it shall (i) provide the filing Party with written notice of its wish, and (ii) continue to offer reasonable assistance to the filing Party in connection with such prosecution or maintenance at no cost to the filing Party except for reimbursement of the non-filing Party's reasonable out-of-pocket expenses incurred by the non-filing Party in rendering such assistance.

(e) The Parties agree to cooperate in the preparation and prosecution of all patent applications filed under Section 15.1.2(a) and 15.1.2(b), including obtaining and executing necessary powers of attorney and assignments by

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the named inventors, providing relevant technical reports to the filing Party concerning the invention disclosed in such patent application, obtaining execution of such other documents which shall be needed in the filing and prosecution of such patent applications, and, as requested, updating each other regarding the status of such patent applications.

15.1.3 Prosecution and Maintenance of GSK Patents. GSK shall have the

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exclusive right and obligation to (subject to GSK's election not to file, prosecute or maintain pursuant to Section 15.1.5) or to cause its licensors to, prepare, file and prosecute in a diligent manner (including without limitation by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees, and other such fees and costs required under applicable Laws) and extend all GSK Patents and related applications. GSK shall consult with Adolor prior to

abandoning any GSK Patents or related applications that are material to the matters contemplated in this Agreement. GSK shall regularly advise Adolor of the status of all pending applications, including with respect to any hearings or other proceedings before any Governmental Authority, and, at Adolor's request, shall provide Adolor with copies of documentation relating to such applications, including all correspondence to and from any Governmental Authority. GSK shall solicit Adolor's advice and review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and GSK shall take into account Adolor's reasonable comments related thereto.

15.1.4 GSK Step-In Rights. If Adolor elects not to file, prosecute or

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maintain the Adolor Patents or claims encompassed by such Adolor Patents necessary for GSK to exercise its rights hereunder in any Country, Adolor shall give GSK notice thereof within a reasonable period prior to allowing such Adolor Patents, or such claims encompassed by such Adolor Patents, to lapse or become abandoned or unenforceable, and GSK shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain such Adolor Patents in such Country.

15.1.5 Adolor Step-In Rights. If GSK elects not to file, prosecute or

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maintain the GSK Patents or claims encompassed by such GSK Patents necessary for Adolor to exercise its rights hereunder in any Country, GSK shall give Adolor notice thereof within a reasonable period prior to allowing such GSK Patents, or such claims encompassed by such GSK Patents, to lapse or become abandoned or unenforceable, and Adolor shall thereafter have the right, at its sole expense, to prepare, file, prosecute and maintain such GSK Patents in such Country.

15.1.6 Execution of Documents by Agents. Each of the Parties shall

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execute or have executed by its appropriate agents such documents as may be necessary to obtain, perfect or maintain any Patent Rights filed or to be filed pursuant to this Agreement, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patent Rights.

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## 15.2 Patent Infringement.

### 15.2.1 Infringement Claims. With respect to any and all Claims

instituted by Third Parties against Adolor or GSK or any of their respective Affiliates for patent infringement involving the use, sale, license or marketing of a Collaboration Product in the United States during the United States Term, \*\* (each, a "Patent Infringement Claim"), \*\*, as applicable, and Adolor and GSK

will assist one another and cooperate in the defense and settlement of such Patent Infringement Claims at the other Party's request.

### 15.2.2 Infringement of Adolor Patents. In the event that Adolor or GSK

becomes aware of actual or threatened infringement of an Adolor Patent during the Term, that Party will promptly notify the other Party in writing (a "Patent

Infringement Notice"). Subject to any Third Party rights existing as of the

Effective Date and in accordance with the Lilly Agreement, Adolor will have the right but not the obligation to bring an infringement action against any Third Party. \*\*. If Adolor elects to pursue such infringement action, Adolor shall be solely responsible for the costs and expenses associated with such action and retain all recoveries. During the Term and subject to any Third Party rights existing as of the Effective Date, in the event that Adolor does not undertake such an infringement action, upon Adolor's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, GSK shall be permitted to do so in Adolor's or the relevant Adolor Affiliate's name and on Adolor's or the relevant Adolor Affiliate's behalf. If Adolor has consented to an infringement action but GSK is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then GSK may join Adolor as party-plaintiff. If GSK elects to pursue such infringement action, Adolor may \*\*

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15.2.3 Infringement of GSK Patents. In the event that GSK or Adolor

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becomes aware of actual or threatened infringement of a GSK Patent during the United States Term, that Party will promptly notify the other Party in writing. GSK will have the right but not the obligation to bring an infringement action against any Third Party. \*\*. If GSK elects to pursue such infringement action, GSK shall be solely responsible for the costs and expenses associated with such action and retain all recoveries. During the United States Term, in the event that GSK does not undertake such an infringement action, upon GSK's written consent, which shall not be unreasonably withheld, refused, conditioned or delayed, Adolor shall be permitted to do so in GSK's or the relevant GSK Affiliate's name and on GSK's or the relevant GSK Affiliate's behalf. If GSK has consented to an infringement action but Adolor is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then GSK may be joined as a party-plaintiff. If Adolor elects to pursue such infringement action, GSK may \*\*.

15.3 Notice of Certification. GSK and Adolor each shall immediately give

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notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (or its foreign equivalent) claiming that a GSK Patent or an Adolor Patent is invalid or that infringement will not arise from the manufacture, use or sale of any Collaboration Product by a Third Party ("Hatch-Waxman Certification").

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15.3.1 Notice. If a Party decides not to bring infringement

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proceedings against the entity making such a certification, such Party shall give notice to the other Party of its decision not to bring suit within

twenty-one (21) days after receipt of notice of such certification.

15.3.2 Option. Such other Party may then, but is not required to,

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bring suit against the entity that filed the certification.

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15.3.3 Name of Party. Any suit by Adolor or GSK shall either be in the

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name of Adolor or in the name of GSK, or jointly in the name of Adolor and GSK, as may be required by law.

15.4 Assistance. For purposes of this Article 15, the Party not bringing

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suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

## ARTICLE 16

### TERM AND TERMINATION

16.1 Term. Unless otherwise mutually agreed to by the Parties, this

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Agreement shall commence on the Effective Date and shall end with respect to the United States, upon expiration of the United States Term, and with respect to the ROW, upon expiration of the last to expire ROW Term, unless terminated sooner as permitted hereunder.

16.2 Extension of Adolor Product Promotion Term. If the Parties agree to

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Develop the OBD Acute Product, or any Additional Product that becomes an Adolor Product, the Adolor Product Promotion Term shall be extended until the sooner to occur of (a) \*\* (\*\*) years following the First Commercial Sale in the United States of the OBD Acute Product or such Additional Product that is designated an Adolor Product, or (b) \*\* (\*\*) years after the First Commercial Sale of the POI Product in the United States.

16.3 Termination for Breach. Either Party may, without prejudice to any

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other remedies available to it at law or in equity, terminate this Agreement with respect to the United States in the event that the other Party (as used in this subsection, the "Breaching Party") shall have materially breached or

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defaulted in the performance of any of its obligations in the United States and with respect to \*\* in the event that the Breaching Party shall have materially breached or defaulted in the performance of its obligations in such \*\*; provided that if such material breach occurs in \*\*, the non-breaching Party may also terminate the \*\*. The Breaching Party shall, if such breach can be cured, have sixty (60) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 60-day period, if the Breaching Party must commence and diligently continue actions to cure such default during such 60-day period). Any such termination shall become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the Breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred twenty (120) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default).

16.4 Termination for Safety Related Reasons. GSK shall be entitled to

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terminate this Agreement, in whole or in part, by giving Adolor sixty (60) days prior written notice if (a) GSK's internal Company Safety Board determines in good faith, consistent with its decision making principles and policies as applied to GSK's internally developed

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products, to permanently cease all Development activities in respect of Compound

for one or more Collaboration Products due to an Adverse Drug Experience and/or

(ii) there are serious adverse events relating to Compound resulting in the withdrawal of an Investigational Authorization or withdrawal of a Marketing Authorization Approval of one or more Collaboration Products in the United States.

16.5 Termination by GSK with Respect to \*\*.

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16.5.1 \*\*. \*\*

16.5.2 \*\*. \*\*

16.5.3 \*\*. \*\*

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16.5.4 \*\*. \*\*

16.6 Termination by Gsk with Respect to \*\*.

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16.6.1 \*\*. \*\*

16.6.2 \*\*. \*\*

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16.6.3 \*\*.

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16.6.4 \*\*. \*\*

16.7 Termination by GSK With Respect to \*\*.

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16.7.1 \*\*. \*\*

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16.7.2 \*\*. \*\*

16.7.3 \*\*. \*\*

16.8 Termination by Adolor. On a Collaboration Product-by-Collaboration

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Product basis, Adolor shall be entitled to terminate this Agreement in the following circumstances:

16.8.1 Adolor Products in the ROW.

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16.8.2 \*\*. \*\*

16.8.3 \*\*. \*\*

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16.8.4 \*\*. \*\*

16.8.5 Delays in Supply of API Compound. In the event that GSK fails

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to achieve any of the timeline events set forth in this Section 16.8 or in the U.S. Development Plan or ROW Development Plan, as applicable, due to a delay by Adolor to supply API Compound necessary to achieve such timeline events, then the timeline shall be extended by a period of time equal to the length of such

delay.

16.9 Effects of Expiration of the Adolor Product Promotion Term. Upon the

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expiration of the Adolor Product Promotion Term, the following shall occur:

16.9.1 Return of Materials. GSK shall promptly transfer to Adolor, at

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Adolor's cost, copies of all data, reports, records and materials for the United States in its possession or control that relate to the Adolor Products and return to Adolor, or destroy at Adolor's request, all relevant records and materials in GSK's possession or control containing Confidential Information of Adolor (provided that GSK may keep one copy of such Confidential Information of Adolor for archival purposes only).

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16.9.2 Transfer of Regulatory Filings. GSK shall transfer to Adolor,

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at Adolor's cost, or shall cause its designee(s) to transfer to Adolor, ownership of all regulatory filings made or filed for such Adolor Products for the United States (to the extent that any are held in GSK's or such designee(s)'s name), if permitted by applicable Laws and regulations.

16.9.3 Return of GSK Confidential Information. Adolor shall promptly

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return to GSK, at GSK's cost, or destroy at GSK's request all relevant records and materials in Adolor's possession or control containing Confidential Information of GSK for the United States relating to the Adolor Products (provided that Adolor may keep one copy of such Confidential Information of GSK for archival purposes only).

16.9.4 License Rights. All licenses granted by Adolor to GSK with

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respect to the Adolor Products under this Agreement for the United States shall be terminated, except for any trademark or trade dress licenses if GSK is

utilizing such Adolor Product Trademark with a GI Product being Commercialized in the United States or with a Collaboration Product being utilized in the ROW.

16.9.5 GI Product Trademarks. In the event that Adolor is utilizing a

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GI Product Trademark in connection with an Adolor Product being Commercialized in the United States, Adolor shall receive a \*\* license to use such GI Product Trademark solely in conjunction with such Adolor Products in the United States.

16.9.6 Use of GSK Housemark and GSK Trade Dress. Adolor's right to

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use the GSK Housemark and GSK trade dress pursuant to Section 2.4.4(b) shall survive expiration of the Adolor Product Promotion Term until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or promotional materials for the Adolor Products in the United States that contain the GSK Housemark or GSK trade dress have been depleted, but in no event for longer than a period of \*\* (\*\*\*) \*\*.

16.10 Effects of Expiration of the GI Product Promotion Term. Upon the

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expiration of the GI Product Promotion Term, the following shall occur:

16.10.1 Return of Confidential Information. Each Party, at its own cost,

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shall promptly return to the other Party, or destroy at the Disclosing Party's request, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party for GI Products in the United States (provided that each Party may keep one copy of such Confidential Information of the other Party for archival purposes only).

16.10.2 License Rights. The licenses granted by Adolor to GSK pursuant to

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Section 2.1 with respect to the GI Products in the United States shall be considered fully-paid and royalty free and in the event that GSK is utilizing an Adolor Product Trademark in connection with a GI Product being Commercialized in the United States, GSK shall receive a \*\* license to use such Adolor

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Product Trademark solely in conjunction with such GI Products in the United States.

16.10.3 Use of Adolor Housemark and Adolor Trade Dress. GSK's right to use

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the Adolor Housemark and Adolor trade dress pursuant to Section 2.4.4(a) shall survive expiration of the GI Product Promotion Term until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or promotional materials for the GI Products in the United States that contain the Adolor Housemark or Adolor trade dress have been depleted, but in no event for longer than a period of \*\* (\*\*\*) \*\*.

16.10.4 Assignment of GI Product Trademarks. In the event that GSK decides

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to no longer Commercialize a GI Product in the United States, GSK shall assign any rights it may have in the GI Product Trademark in the United States to Adolor and Adolor shall pay to GSK a trademark royalty of \*\* percent (\*\*%) on Net Sales of GI Products in the United States for so long as Adolor uses such assigned GI Product Trademark in the United States in conjunction with the sale of GI Products.

16.11 Effects of Expiration of the ROW Term. Upon the expiration of the ROW

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Term, on a Collaboration Product-by-Collaboration Product and Country-by-Country basis, the following shall occur:

16.11.1 Return of Confidential Information. Each Party, at its own cost,

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shall promptly return to the other Party, or destroy at the Disclosing Party's request, all relevant records and materials in such Party's possession or control containing Confidential

Information of the other Party (provided that each Party may keep one copy of such Confidential Information of the other Party for archival purposes only).

16.11.2 License Rights. The licenses granted by Adolor to GSK pursuant to

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Section 2.1 with respect to the Collaboration Products in the ROW shall be considered \*\*.

16.11.3 Adolor Product Trademarks.

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(a) GSK shall, at its own expense, assign to Adolor the Adolor Products Trademarks which were used in connection with a Collaboration Product in respect to those applicable Countries in the ROW in which GSK owns the Adolor Product Trademarks in such Country. Upon such assignment, Adolor shall grant GSK an exclusive license to use such Adolor Product Trademarks in connection with such Collaboration Product in respect to those applicable Countries in the ROW on the terms set forth in Section 16.11.3(b).

(b) GSK shall pay Adolor a trademark royalty of \*\* percent (\*\*%) on Net Sales of Collaboration Products in the applicable Country of the ROW for so long as GSK uses an Adolor Product Trademark in the ROW in

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conjunction with the sale of Collaboration Products under the license granted in Section 16.11.3(a).

16.11.4 Use of Adolor Housemark or Adolor Trade Dress. GSK's right to use

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the Adolor Product Trademark (having assigned the same to Adolor in accordance with the terms of this Agreement), the Adolor Housemark and the Adolor trade dress pursuant to Section 2.4.4(a) shall survive expiration of the ROW Term until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or promotional materials for the Collaboration

Products in the applicable Country of the ROW that contain the Adolor Housemark, the Adolor Product Trademarks or Adolor trade dress have been depleted, but in no event for longer than a period of \*\* (\*\*\*) \*\*.

16.11.5 Assignment of ROW Trademarks. In the event that GSK decides to no

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longer Commercialize a Collaboration Product in the ROW, GSK shall assign, at Adolor's cost, any rights it may have in the GI Product Trademarks or ROW Trademarks, as applicable, to Adolor and Adolor shall pay to GSK a trademark royalty of \*\* percent (\*\*%) on Net Sales of Collaboration Products in the ROW for so long as Adolor uses such assigned GI Product Trademark or ROW Trademark, as applicable, in the ROW in conjunction with the sale of Collaboration Products.

16.12 Effect of Termination. On a Collaboration Product-by-Collaboration

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Product and/or on a \*\* and/or United States basis, in the event that this Agreement is terminated (in which case such Collaboration Products so terminated in such Major Region and/or the United States shall, for purposes of this Section 16.12, be referred to as a "Terminated Collaboration Product"), the

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following shall occur:

16.12.1 Return of Materials. GSK shall, at its sole expense,

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promptly transfer to Adolor copies of all data, reports, records and materials in its possession or control that relate to the Terminated Collaboration Product and return to Adolor, or destroy at Adolor's request, all relevant records and materials in its possession or control containing Confidential Information of Adolor (provided that GSK may keep one copy of such Confidential Information of Adolor for archival purposes only).

16.12.2 Transfer of Regulatory Filings. GSK shall, at its sole

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expense, transfer to Adolor, or shall cause its designee(s) to transfer to Adolor, ownership of all regulatory filings made or filed for the Terminated

Collaboration Product (to the extent that any are held in GSK's or such designee(s)'s name), if permitted by applicable Laws and regulations.

16.12.3 License Rights. Subject to Section 16.12.6, all licenses

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granted by Adolor to GSK with respect to the applicable Terminated Collaboration Product in the applicable \*\* under this Agreement shall be terminated.

16.12.4 Assignment of Rights in the Adolor Product Trademarks, GI

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Product Trademarks, ROW Trademarks and Promotional Material. GSK shall, at its

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own expense,

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assign to Adolor any rights it may have in the GI Product Trademarks and/or the ROW Trademarks and corresponding promotional materials to the extent that the foregoing relate to the Terminated Collaboration Product, and all such trademarks and rights in the promotional materials shall be owned by Adolor. GSK shall, at its own expense, assign to Adolor the Adolor Product Trademarks which were used in connection with a Terminated Collaboration Product in respect of those Countries in the ROW in which GSK owns the Adolor Product Trademarks.

16.12.5 Manufacturing. For a Terminated Collaboration Product then

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being manufactured by or on behalf of GSK, the Parties shall, at Adolor's sole discretion, (a) negotiate, in good faith, a supply agreement for such Terminated Collaboration Product on commercially reasonable terms, or (b) transfer any required technology to Adolor or its designee to enable Adolor or such designee to manufacture such Terminated Collaboration Product; provided that, in any event, GSK shall ensure, for up to \*\* (\*\*) \*\*, that Adolor has a continuous and uninterrupted supply of such Terminated Collaboration Product until such supply agreement or transition is accomplished.

16.12.6 Transfer of Inventory. Adolor shall be entitled to decide,

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within its reasonably exercised discretion, whether (i) GSK shall sell to Adolor or its designee at cost all remaining inventory of the Terminated Collaboration Product which are in good saleable condition, or (ii) GSK shall be entitled to sell out such remaining inventory under the conditions set forth in this Agreement, including all payment obligations, during a period of six (6) months after termination. Inventory of the Terminated Collaboration Product not sold to Adolor or inventory not sold out by GSK shall be destroyed at GSK's sole cost and expense. If Adolor decides to elect for item (ii) herein, GSK's rights to use the Adolor Housemark pursuant to Section 2.4.4(b) and, to the extent applicable, and, without prejudice to any other provision of this Agreement, the GI Product Trademarks and the Adolor Product Trademarks shall survive termination until expiry of such six (6) month period or, if earlier, until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or promotional materials for the Terminated Collaboration Product that contain the Adolor Housemark has been depleted.

16.12.7 Transition During Notice Period. During the notice periods

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required pursuant to Section 16.5.1, 16.5.2, 16.5.4, 16.6.1, 16.6.2, 16.6.4, 16.7.2, 16.7.3 or 16.8, GSK shall be obligated to maintain its Commercially Reasonable Efforts to Develop or Commercialize the Terminated Collaboration Product in accordance with the applicable U.S. Marketing Plans and undertake all reasonable efforts to transition any such activities to Adolor to enable Adolor to continue the Development or Commercialization of the Terminated Collaboration Product after such applicable notice period.

16.12.8 Use of GSK Housemark or GSK Trade Dress. Adolor's right

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to use the GSK Housemark and GSK trade dress pursuant to Section 2.4.4(b) shall survive termination until such time as any existing inventory of labeling, package inserts

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.



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or outserts, monographs or packaging materials or promotional materials for the Terminated Collaboration Product that contain the GSK Housemark or GSK trade dress have been depleted, but in no event for longer than a period of \*\* (\*\*) \*\*.

16.13 Effect of Termination for Safety Related Reasons. In the event that

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GSK terminates this Agreement pursuant to Section 16.4, the Parties, in good faith, shall cooperate and mutually agree as to the disposition of the Collaboration Products.

16.14 General Effects of Termination.

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16.14.1 Milestone Payments. GSK shall not be obligated to make a

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Development Milestone payment under Section 6.2 which is triggered by an event occurring after the effective date of termination of this Agreement.

16.14.2 Accrued Rights; Surviving Obligations. Termination,

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relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment or expiration.

## ARTICLE 17

### LIMITATIONS ON PURCHASES OF EQUITY SECURITIES

17.1 Purchases of Equity Securities. During the Term and for a period of

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one (1) year thereafter, except as permitted by Section 17.2, GSK and its Affiliates will not (and will not assist or encourage others to) directly or

indirectly in any manner:

17.1.1 acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or interest in any

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securities or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any securities of Adolor;

17.1.2 make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the Securities and Exchange Commission (the "SEC") promulgated pursuant to Section 14 of the Exchange Act); provided,

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however, that the prohibition in this Section 17.1.2 shall not apply to solicitations exempted from the proxy solicitation rules by Rule 14a-2 under the Exchange Act as such Rule 14a-2 is in effect as of the date hereof;

17.1.3 form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of Adolor;

\*\*=Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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17.1.4 acquire or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, exchange or otherwise, (i) any of the assets, tangible or intangible, of Adolor or (ii) direct or indirect rights, warrants or options to acquire any assets of Adolor, except for such assets as are then being offered for sale by Adolor;

17.1.5 enter into any arrangement or understanding with others to do any of the actions restricted or prohibited under Sections 17.1.1, 17.1.2 or 17.1.3; or

17.1.6 otherwise act in concert with others, to seek to offer to Adolor or any of its stockholders any business combination, restructuring,

recapitalization or similar transaction to or with Adolor or otherwise seek in concert with others, to control, change or influence the management, board of directors or policies of Adolor or nominate any person as a director of Adolor who is not nominated by the then incumbent directors, or propose any matter to be voted upon by the stockholders of Adolor.

17.2 Exceptions for Purchasing Securities of Adolor. Nothing herein shall

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prevent:

17.2.1 GSK from purchasing additional equity security of Adolor if after such purchase GSK and its Affiliates would own no greater percent of the total voting power of all voting securities of Adolor then outstanding than GSK owned immediately prior to the Effective Date.

17.2.2 GSK from acquiring securities of Adolor issued in connection with stock splits or recapitalizations or on exercise of pre-emptive rights afforded to Adolor stockholders generally.

17.2.3 GSK or GSK's employees from purchasing securities of Adolor pursuant to (i) a pension plan established for the benefit of GSK's employees, (ii) any employee benefit plan of GSK or (iii) any stock portfolios not controlled by GSK or any of its Affiliates that invest in Adolor among other companies.

17.2.4 GSK from acquiring securities of another biotechnology or pharmaceutical company that beneficially owns any of Adolor's securities.

17.2.5 GSK or any of its Affiliates from acquiring equity securities of Adolor without any limitation following initiation by a third party of an unsolicited tender offer to purchase \*\* percent (\*\*%) or more of any class or service of Adolor's publicly traded voting securities (a "Hostile Tender

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Offer"); provided that the exception provided by this Section 17.2.5 shall be

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limited to the classes or series of Adolor's securities that are the subject of the Hostile Tender Offer; provided, further, that, in the event that either (a) such Hostile Tender Offer is terminated or expires without the purchase of at least \*\* percent (\*\*%) of any class or series of Adolor's publicly traded voting securities by such third party, or (b) the Adolor Board of Directors

subsequently recommends that such offer be accepted, then GSK shall divest in one or more open-market transactions all shares of Adolor's securities so acquired by it. Any such divestiture shall be completed as expeditiously as possible consistent with applicable securities laws and

\*\* = Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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regulations and in a manner intended to shield GSK from liability for recovery of short swing profits under Section 16 of the Exchange Act and the rules promulgated thereunder.

#### ARTICLE 18

##### MISCELLANEOUS

18.1 Relationship of the Parties. Each Party shall bear its own costs

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incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, GSK's legal relationship under this Agreement to Adolor shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

18.2 Registration and Filing of this Agreement. To the extent, if any, that

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either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority, including without limitation the U.S. Securities and Exchange

Commission, the Competition Directorate of the Commission of the European Communities or the U.S. Federal Trade Commission, in accordance with Law, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

18.3 Force Majeure. The occurrence of an event which materially interferes

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with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of due diligence have been avoided (each, a "Force

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Majeure Event"), including, but not limited to, an injunction, order or action

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by a Governmental Authority, fire, accident, labor difficulty, strike, riot, civil commotion, act of God, inability to obtain raw materials, delay or errors by shipping companies or change in law, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the continuation of the force majeure. The Party prevented from performing its obligations or duties because of a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such force majeure and shall provide the other

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Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected

shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 18.3.

18.4 Governing Law. This Agreement shall be construed, and the respective

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rights of the Parties determined, according to the substantive law of the State of Delaware notwithstanding the provisions governing conflict of laws under such Delaware law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property laws relevant to the intellectual property in question. The UNCITRAL Convention for the International Sale of Goods, as well as any other unified law relating to the conclusion and implementation of contracts for the international sale of goods, shall not apply.

18.5 Dispute Resolution; Arbitration.

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18.5.1 Dispute Resolution. For disputes not subject to Section 3.1.4,

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any dispute, controversy or claim arising out of or relating to this Agreement which the Parties are unable to amicably settle themselves shall first be submitted to the Joint Steering Committee for resolution. The Joint Steering Committee shall have thirty (30) days to attempt to resolve the dispute and will set forth any resolution in writing. If the Joint Steering Committee is unable to resolve the dispute within the thirty (30) day period, the dispute shall automatically be referred to the Officers within seventy-two (72) hours, and such Officers shall attempt to resolve the dispute within a reasonable time, but in no case more than forty-five (45) days from the time that the Joint Steering Committee forwards its resolution to the Officers. The Officers shall issue

their resolution in writing.

18.5.2 Arbitration. Any dispute, controversy or claim arising out of

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or relating to this Agreement which the Parties have not resolved under Section

18.5.1, including, without limitation, disputes relating to (i) the validity,

inducement or breach of or the interpretation of any provision of this

Agreement, (ii) the interpretation or application of law or (iii) the ownership

of any intellectual property, shall be decided by arbitration in accordance with

the International Rules of the American Arbitration Association ("AAA") for

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Commercial Arbitration in effect at the time the dispute arises, unless the

Parties hereto mutually agree otherwise. To the extent such rules are

inconsistent with this provision, this provision will control.

(a) Any demand for arbitration must be made in writing to the

other Party.

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(b) There will be a panel of three arbitrators, one selected

by Adolor, one selected by GSK, and one selected by mutual agreement of the

arbitrators selected by Adolor and GSK. If the arbitrators selected by Adolor

and GSK cannot agree on a third arbitrator within thirty (30) days, then the AAA

shall select the third arbitrator. Any arbitration involving patent rights,

other intellectual property rights or intellectual property shall be heard by

arbitrators who are experts in such areas.

(c) The arbitration shall be held in Wilmington, Delaware, or

such other place as the Parties agree. The arbitrators shall apply the

substantive law of Delaware in accordance with Section 18.4, without regard to

conflicts of laws and except that the interpretation and enforcement of this

arbitration provision shall be governed by the Federal Arbitration Act.

(d) Neither Party shall have the right independently to seek

recourse from a court of law or other authorities in lieu of arbitration, but

each Party has the right before or during the arbitration to seek and obtain

from the appropriate court provisional remedies to avoid irreparable harm,

maintain the status quo or preserve the subject matter of the arbitration. There

shall be a stenographic record of the proceedings. The decision of the arbitrators shall be made by majority vote and shall be final and binding upon both Parties. The arbitrators shall render a written opinion setting forth findings of fact and conclusions of law.

18.5.3 Expenses of Arbitration. The expenses of the arbitration shall

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be borne by the Parties in proportion as to which each Party prevails or is defeated in arbitration. Each Party shall bear the expenses of its counsel and other experts.

18.6 Assignment. This Agreement may not be assigned by either Party without

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the prior consent of the other Party; provided, however that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and provided further that either Party may assign this Agreement to a successor to all or substantially all of the assets of such Party whether by merger, sale of stock, sale of assets or other similar transaction. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

18.7 Notices. All demands, notices, consents, approvals, reports, requests

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and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Adolor: Adolor Corporation

620 Pennsylvania Drive

Exton, Pennsylvania 19341

Facsimile: 484-595-1520

Attn: President

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With a copy to: Morgan, Lewis & Bockius LLP



502 Carnegie Center

Princeton, NJ 08540

Attn: Randall B. Sunberg

Facsimile: 609-919-6639

and with a copy to: Dechert

4000 Bell Atlantic Tower

1717 Arch Street

Philadelphia, PA 19103

Attn: James A. Lebovitz

Facsimile: 215-994-2222

GSK: Glaxo Group Limited

Glaxo Wellcome House

Berkeley Avenue

Greenford

Middlesex

UB6 0NN

United Kingdom

Attn: Company Secretary

Facsimile: 011 44 208-047-6912

With a copy to: GlaxoSmithKline plc

980 Great West Road

Brentford

Middlesex

TW8 9GS

United Kingdom

Attn: Corporate Law

Facsimile: 011 44 208-047-6912

and with a copy to: GlaxoSmithKline plc

980 Great West Road

Brentford

Middlesex

TW8 9GS

United Kingdom

Attn: Vice President, Worldwide Business Development

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or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

18.8 Severability. In the event of the invalidity of any provisions of this

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Agreement or if this Agreement contains any gaps, the Parties agree that such invalidity or gap shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision or fill any gap with valid provisions which most closely approximate the purpose and economic effect of the invalid provision or, in case of a gap, the Parties' presumed intentions. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable laws, rules or regulations.

18.9 Headings. The headings used in this Agreement have been inserted

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for convenience of reference only and do not define or limit the provisions hereof.

18.10 Waiver. Any term or condition of this Agreement may be waived at

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any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

18.11 Entire Agreement. This Agreement (including the exhibits and

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schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Adolor and GSK.

18.12 No License. Nothing in this Agreement shall be deemed to constitute

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the grant of any license or other right in either Party, to or in respect of any Collaboration Product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

18.13 Third Party Beneficiaries. None of the provisions of this Agreement

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shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

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18.14 Counterparts. This Agreement may be executed in any two

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counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document.

[Signature Page Follows]

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IN WITNESS WHEREOF, Adolor and GSK, by their duly authorized officers, have executed this Agreement as of the Effective Date.

ADOLOR CORPORATION GLAXO GROUP LIMITED

By: /s/ John J. Farrar By: /s/ J.P. Garnier

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Name: John J. Farrar Name: J.P. Garnier

Title: President and Title: Chief Executive

Chief Executive Officer

Officer

SIGNATURE PAGE TO COLLABORATION AGREEMENT