Dealdoc

Co-development and licensing agreement for Folotyn

Allos Therapeutics
Mundipharma

May 10 2011
Co-development and licensing agreement for Folotyn

Companies: Allos Therapeutics
Mundipharma

Announcement date: May 10, 2011
Deal value, US$m: 360.5 : sum of upfront and milestone payments
Related contracts: Supply agreement for Folotyn

Details

Announcement date: May 10, 2011
Start date: May 10, 2011
Industry sectors: Pharmaceutical
Therapy areas: Oncology » Lymphoma
Technology types: Small molecules
Co-development
Deal components: Development
Licensing
Stages of development: Regulatory
Geographic focus: Worldwide
Excluded geography: North America » Canada

Financials

Deal value, US$m: 360.5 : sum of upfront and milestone payments
Upfront, US$m: 50.0 : upfront payment
Milestones, US$m: 310.5 : regulatory and commercial progress- and sales-dependent milestone payments
Royalty rates, %: n/d : tiered double-digit royalties based on net sales of FOLOTYN within Mundipharma licensed territories
n/d : Allos and Mundipharma will jointly fund development costs initially on a 60:40 basis
n/d : change to a 50:50 basis if certain predefined milestones are achieved including approval of the MAA currently under review to market FOLOTYN in the European Union
Funding, US$m: n/d

Termsheet

Strategic collaboration agreement to co-develop FOLOTYN® (pralatrexate injection).

Allos retains full commercialization rights for FOLOTYN in the United States and Canada, with Mundipharma having exclusive rights to commercialize FOLOTYN in all other countries.

Allos will receive an upfront payment of $50 million and potential regulatory and commercial progress- and sales-dependent milestone payments of up to $310.5 million.

Allos is also entitled to receive tiered double-digit royalties based on net sales of FOLOTYN within Mundipharma’s licensed territories.
Allos and Mundipharma will jointly fund development costs, initially on a 60:40 basis, which will change to a 50:50 basis if certain pre-defined milestones are achieved, including approval of the MAA currently under review to market FOLOTYN in the European Union.

Development funding by Mundipharma will support jointly agreed-upon clinical development activities, including, but not limited to, the planned Phase 3 studies of FOLOTYN in previously undiagnosed PTCL and in combination with bexarotene in relapsed or refractory cutaneous T-cell lymphoma (CTCL).

Pursuant to a separate supply agreement with Mundipharma Medical Company, an affiliate of Mundipharma, Allos will supply FOLOTYN for Mundipharma’s clinical and commercial uses.

Press Release

Allos Therapeutics and Mundipharma Announce Strategic Collaboration for FOLOTYN

– Allos to Receive $50 Million Upfront Payment and Retain Full Commercialization Rights to FOLOTYN in U.S. and Canada; Mundipharma to Co-Develop and Commercialize in the Rest of World –

– Allos to Host Conference Call Today at 4:30 p.m. Eastern Time to Discuss Collaboration and Q1 Financial Results –

WESTMINSTER, Colo.--(BUSINESS WIRE)--Allos Therapeutics, Inc. (NASDAQ: ALTH) and Mundipharma International Corporation Limited (Mundipharma) today jointly announced that the companies have entered into a strategic collaboration agreement to co-develop FOLOTYN® (pralatrexate injection). Under the agreement, Allos retains full commercialization rights for FOLOTYN in the United States and Canada, with Mundipharma having exclusive rights to commercialize FOLOTYN in all other countries.

FOLOTYN, a folate analogue metabolic inhibitor, is the first and only drug approved in the United States for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), a biologically diverse group of aggressive blood cancers, and is being studied in a number of other hematologic malignancies. Allos is pursuing regulatory approval to market FOLOTYN in the European Union for relapsed or refractory PTCL. Allos’ Marketing Authorisation Application (MAA) was accepted for review by the European Medicines Agency (EMA) in December 2010.

Under the collaboration, Allos will receive an upfront payment of $50 million and potential regulatory and commercial progress- and sales-dependent milestone payments of up to $310.5 million. Allos is also entitled to receive tiered double-digit royalties based on net sales of FOLOTYN within Mundipharma’s licensed territories. Allos and Mundipharma will jointly fund development costs, initially on a 60:40 basis, which will change to a 50:50 basis if certain pre-defined milestones are achieved, including approval of the MAA currently under review to market FOLOTYN in the European Union. Development funding by Mundipharma will support jointly agreed-upon clinical development activities, including, but not limited to, the planned Phase 3 studies of FOLOTYN in previously undiagnosed PTCL and in combination with bexarotene in relapsed or refractory cutaneous T-cell lymphoma (CTCL). Pursuant to a separate supply agreement with Mundipharma Medical Company, an affiliate of Mundipharma, Allos will supply FOLOTYN for Mundipharma’s clinical and commercial uses.

"Mundipharma is an ideal global partner. They have demonstrated hematology/oncology development, regulatory and commercial capabilities with recent major regulatory and commercial successes in bringing Levact® (bendamustine) to market in Europe for non-Hodgkin lymphoma and other blood cancers, as well as substantial resources to develop and commercialize FOLOTYN," said Paul L. Berns, president and chief executive officer of Allos Therapeutics, Inc. "We are currently seeking regulatory approval to market FOLOTYN in Europe for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. Our two companies share a vision for bringing FOLOTYN to patients and believe this collaboration will maximize the development, commercialization and market potential of FOLOTYN in a variety of blood cancers."

"Mundipharma is delighted to partner with Allos in the development and commercialization of FOLOTYN and believes that it has worldwide potential to become an important treatment alternative for patients," commented Åke Wikström, regional director Europe at Mundipharma International Limited. “FOLOTYN represents a very meaningful addition to Mundipharma’s oncology pipeline and reinforces our commitment to improving patients’ quality of life.”

"Lymphoma arising from T-lymphocytes remains a devastating disease and new treatments are urgently needed. FOLOTYN, if approved, may be in many countries the first drug to treat this cancer and this will allow us to work with haematologists to improve the treatment results by developing new and hopefully even more effective drug combinations,” added Dr. Thomas Mehrling, director of European Oncology at Mundipharma International Limited.

About FOLOTYN

FOLOTYN, a folate analogue metabolic inhibitor, was discovered by Sloan-Kettering Institute for Cancer Research, SRI International and Southern Research Institute and developed by Allos Therapeutics. In September 2009, the U.S. Food and Drug Administration (FDA) granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory PTCL. This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated. FOLOTYN has been available to patients in the U.S. since October 2009. An updated analysis of data from PROPEL was published in the March 20, 2011 issue of the Journal of Clinical Oncology.
FDA’s accelerated approval program allows the FDA to approve products for cancer or other life-threatening diseases based on initial positive clinical data. In connection with the accelerated approval, Allos is required to conduct post-approval studies that are intended to verify and describe the clinical benefit of FOLOTYN in patients with T-cell lymphoma. In March 2011, Allos reached agreement with the FDA under its Special Protocol Assessment (SPA) process for the design of Allos’ Phase 3 clinical trial of FOLOTYN in patients with previously undiagnosed PTCL. The study will seek to enroll newly diagnosed patients with PTCL who have achieved a response following initial treatment with a CHOP-based therapy.

Allos is also pursuing regulatory approval to market FOLOTYN in the European Union for relapsed or refractory PTCL. Allos’ MAA was accepted for review by the EMA in December 2010.

Conference Call Information

Allos will host a conference call today, May 10, 2011 at 4:30 p.m. ET, to review its first quarter 2011 financial results and to discuss the details of the collaboration with Mundipharma. Participants can access the call at 1-877-941-1466 (U.S.) or +480-629-9724 (Canada and international). To access the live audio webcast or the subsequent archived recording, visit the “Investors - Presentations and Events” section of the Allos website at www.allos.com. Webcast and telephone replays of the conference call will be available approximately two hours after the completion of the call. Callers can access the replay by dialing 800-406-7325 (domestic) or 303-590-3030 (international). The passcode is 4438057#. The webcast will be recorded and available for replay on Allos’ website until May 24, 2011.

About Peripheral T-Cell Lymphoma

T-cell lymphomas comprise a biologically diverse group of blood cancers that account for approximately 10% to 15% of all cases of non-Hodgkin lymphomas (NHL).1-3 Allos estimates the current annual incidence of PTCL to be approximately 5,900 patients in the U.S. and approximately 6,000-7,000 patients in the top five European markets. The outcome of patients with PTCL is poor and the majority of patients ultimately have refractory disease to a variety of agents, including multi-agent chemotherapy with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or CHOP-like regimens. The 5-year overall survival rate in these patients is 25% to 40%, depending on sub-type.4-5

About Allos Therapeutics

Allos Therapeutics, Inc. (Nasdaq: ALTH) is a biopharmaceutical company committed to the development and commercialization of innovative anti-cancer therapeutics. Allos is currently focused on the development and commercialization of FOLOTYN® (pralatrexate injection), a folate analogue metabolic inhibitor. FOLOTYN is the first and only drug approved in the U.S. for the treatment of patients with relapsed or refractory PTCL. Allos is also developing FOLOTYN in other hematologic malignancies and solid tumors. Allos is headquartered in Westminster, CO. For additional information, please visit www.allos.com.

About Mundipharma

Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies – privately owned companies and joint ventures covering the world’s pharmaceutical markets. These companies worldwide are dedicated to bringing to patients with severe and debilitating diseases the benefits of novel treatment options in fields such haemato-oncology, severe pain and respiratory disease. For more information, visit www.mundipharma.co.uk.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If ≥Grade 2 mucositis is observed, omit or modify dose. Patients should be instructed to take folic acid and receive vitamin B12 to potentially reduce treatment-related hematological toxicity and mucositis.

Fatal dermatologic reactions may occur. Dermatologic reactions may be progressive and increase in severity with further treatment. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued.

Tumor lysis syndrome may occur. Monitor patients and treat if needed.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN and pregnant women should be informed of the potential harm to the fetus.

Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment.

Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are ≥Grade 3, omit or modify dose.

Adverse Reactions
The most common adverse reactions were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events are pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea, and thrombocytopenia.

Use in Specific Patient Population

Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

Drug Interactions

Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethoxazole) may result in delayed renal clearance.

Please see FOLOTYN Full Prescribing Information at www.FOLOTYN.com.

Filing Data

Not available.

Contract

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

by and between

ALLOS THERAPEUTICS, INC.,

a Delaware corporation

and

MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED

a Bermuda corporation

[ * ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (this “Agreement”) is entered into as of May 10, 2011 (the “Effective Date”) by and between ALLOS THERAPEUTICS, INC., a Delaware corporation having a place of business at 11080 Circle Point Road, Suite 200, Westminster, Colorado 80020, U.S. (“Allos”), and MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED, a Bermuda corporation having a place of business at Mundipharma House, 14 Par-la-Ville Road, P.O. Box HM 2332, Hamilton HM JX, Bermuda.
RECITALS

WHEREAS, Allos has rights to a proprietary anti-folate product known as pralatrexate (tradename Folotyn), which has received an accelerated regulatory approval in the U.S. for treatment of patients with relapsed or refractory peripheral T-cell lymphoma and for which a Drug Approval Application has been submitted to the European Medicines Agency for treatment of patients with relapsed or refractory peripheral T-cell lymphoma;

WHEREAS, Mundipharma possesses resources and expertise in the development, manufacture, marketing and commercialization of pharmaceutical products;

WHEREAS, Allos and Mundipharma desire to collaborate to pursue regulatory approval of Folotyn for relapsed or refractory peripheral T-cell lymphoma by the EMA, and in other countries in the Licensed Territory, and to collaborate in the development of Folotyn in other Oncology Indications, all pursuant to a mutually agreed development plan, with Mundipharma having exclusive rights to develop and commercialize Folotyn for all indications in the Licensed Territory, and Allos retaining all other Folotyn commercialization rights, all on the terms and conditions set forth herein; and

WHEREAS, Mundipharma or its designee and Allos are also entering into a separate supply agreement of even date herewith (the “Supply Agreement”), pursuant to which Mundipharma or its designee will be purchasing its requirements of Folotyn from Allos and Allos will be supplying Folotyn to Mundipharma or its designee on the terms and conditions set forth therein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

1.1 “50/50 Threshold” has the meaning set forth in Section 4.5.

1.2 “Acquiror” has the meaning set forth in Section 14.5.

1.3 “Active Pharmaceutical Ingredient” or “API” means [ * ].

1.4 “Additional Study” has the meaning set forth in Section 4.4(a).

1.5 “Adverse Event” has the meaning set forth in Section 5.7(b).

1.6 “Affiliate” means, with respect to either Party, any person, firm, trust, corporation, partnership or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party; the term “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) meaning direct or indirect ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof.

1.7 “Allos Change of Control Notice” has the meaning set forth in Section 12.4(a)(ii).

1.8 “Allos-Facilitated ISS” means an ISS that Allos authorizes or facilitates in accordance with Section 4.7.

1.9 “Allos Indemnitees” has the meaning set forth in Section 10.2.

1.10 “Allos ISS Technology” means (a) all Information that (i) is necessary or useful for the Development or Commercialization of a Product in the Field, (ii) is Controlled by Allos or its Affiliates during the Term, and (iii) arises from an Allos-Facilitated ISS, and (b) any Patent (other than a Joint Patent) that (x) claims the Product or the API or the manufacture or use in the Field of the Product or the API, (y) is Controlled by Allos or its Affiliates during the Term, and (z) claims an invention arising from an Allos-Facilitated ISS; provided, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Allos after the Effective Date due to a Change of Control of Allos, except to the extent such Third Party’s Information or Patents are Controlled by Allos (or its Acquiror) or any of its other Affiliates and are necessary for the Development or Commercialization of the Product and are utilized in respect of the Product or the API in the Allos Territory.
1.11 “Allos Know-How” means all Information that (a) is necessary or useful for the Development or Commercialization of a Product in the Field but is not directed to the manufacture of a Product and (b) (i) is Controlled by Allos or its Affiliates as of the Effective Date or (ii) is Controlled by Allos or its Affiliates during the Term and arises from a Shared Study (including any Incremental Study that becomes an Additional Study upon Mundipharma’s exercise of the Opt-In Right under Section 4.4(c)(v)); provided, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Allos after the Effective Date due to a Change of Control of Allos, except to the extent such Third Party’s Information is Controlled by Allos (or its Acquiror) or any of its other Affiliates and is necessary for the Development or Commercialization of the Product and is utilized in respect of the Product or the API in the Allos Territory; and provided further that, “Allos Know-How” excludes (x) Information arising from any Incremental Study (with respect to which Mundipharma does not exercise its Opt-In Right under Section 4.4(c)(v)) or Investigator-Sponsored Study, and (y) Allos Manufacturing Know-How.

1.12 “Allos Manufacturing Know-How” means all Information that is necessary or useful for the manufacture and quality testing of a Product in the Field and is Controlled by Allos or its Affiliates as of the Effective Date or during the Term; provided, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Allos after the Effective Date due to a Change of Control of Allos, except to the extent such Third Party’s Information is Controlled by Allos (or its Acquiror) or any of its other Affiliates and is necessary for the manufacture of, and is utilized by or on behalf of Allos in respect of, the Product or the API in the Allos Territory or the Licensed Territory.

1.13 “Allos Patent” means any Patent (other than a Joint Patent) that (a) claims the Product or the API or the manufacture or use in the Field of the Product or the API and (b) (i) is Controlled by Allos or its Affiliates as of the Effective Date, (ii) is Controlled by Allos or its Affiliates during the Term and claims priority to a Patent Controlled by Allos or its Affiliates as of the Effective Date, or (iii) is Controlled by Allos or its Affiliates during the Term and claims an invention arising from a Shared Study (including any Incremental Study that becomes an Additional Study upon Mundipharma’s exercise of the Opt-In Right under Section 4.4(c)(v)); provided, each Allos Patent in existence on the Effective Date is set forth in Schedule 1 hereto; and provided further that (i) the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate of Allos after the Effective Date due to a Change of Control of Allos, except to the extent such Third Party’s Patents are Controlled by Allos (or its Acquiror) or any of its other Affiliates and are necessary for the Development, Commercialization or manufacture of the Product and are utilized in respect of the Product or the API in the Allos Territory and (ii) “Allos Patent” excludes any Patent that claims an invention arising from an Incremental Study (with respect to which Mundipharma does not exercise its Opt-In Right under Section 4.4(c)(v)) or Investigator-Sponsored Study.

1.14 “Allos Payment-Allos Withholding Tax Action” has the meaning set forth in Section 7.10(d)(i).

1.15 “Allos Payment-Mundipharma Withholding Tax Action” has the meaning set forth in Section 7.10(d)(ii).

1.16 “Allos Prosecuted Patents” has the meaning set forth in Section 8.3(a).

1.17 “Allos Share” means that percentage which is equal to the remainder when the Mundipharma Share is subtracted from one hundred percent (100%). For clarity, the Allos Share will be sixty percent (60%) when the Mundipharma Share is forty percent (40%) and the Allos Share will be fifty percent (50%) when the Mundipharma Share is fifty percent (50%).

1.18 “Allos Shortfall Event” has the meaning set forth in Section 12.4(d).

1.19 “Allos Studies” has the meaning set forth in Section 4.2(b).

1.20 “Allos Technology” means the Allos Know-How, Allos Patents and Allos’ interest in Joint Patents.

1.21 “Allos Territory” means the U.S. and Canada and any country(ies) that is/are removed from the Licensed Territory and transferred to the Allos Territory in accordance with Section 6.6(b).

1.22 “Allos Territory Infringement” has the meaning set forth in Section 8.5(a).

1.23 “Allos Unpaid Reimbursement Amount” means, if Allos fails to pay the Allos Share of Joint Development Costs within [*] after delivery by Mundipharma of an invoice to Allos for the Allos Share of Joint Development Costs pursuant to Section 7.2(b) (provided that Allos does not,
within [*] after Allos receives such invoice, have a bona fide, good faith dispute in respect thereof), then [*] of the sum of the unpaid Allos Share of Joint Development Costs and interest on such unpaid Allos Share of Joint Development Costs from the date originally due as provided in Section 7.7.

1.24 “ATLL” means [*].

1.25 “Bankruptcy Code” means, as applicable, the U.S. Bankruptcy Code, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder or the bankruptcy laws of any Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

1.26 “Breaching Party” has the meaning set forth in Section 12.2.

1.27 “Bulk Product” has the meaning set forth in the Supply Agreement.

1.28 “Canada” means Canada, including all possessions and territories thereof.

1.29 “Change of Control” means, with respect to either Party, (i) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; (ii) a merger, consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party immediately prior to such merger, consolidation, share exchange or other similar transaction ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (iii) the acquisition by a person or entity, or group of persons or entities acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of such Party; in all cases of clauses (i)-(iii), where such transaction is to be entered into with any person or group of persons other than the other Party or its Affiliates.

1.30 “Claims” has the meaning set forth in Section 10.1.

1.31 “Clinical Proof of Concept” means availability of human clinical data confirming that the concept of a new Indication is feasible and that further investigation is reasonably likely to be capable of Drug Approval and Commercialization; provided, such data,

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

with respect to new Indications, shall include efficacy and safety data from a Phase 1 Study, Phase 1/2 study and/or Phase 2 Study, or, with respect to new formulations or routes of administration, shall include pharmacokinetic data from Phase 1 Studies.

1.32 “CMC Information” means Information related to the chemistry, manufacturing and controls of the Product, as specified by the FDA, EMA and other applicable Regulatory Authorities.

1.33 “Commercialization”, with a correlative meaning for “Commercialize” and “Commercializing”, means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, medical education and medical liaison activities, marketing, pricing, reimbursement, sale and distribution of the Product, including strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support, and all customer support, Product distribution, invoicing and sales activities; provided, however, “Commercialization” shall exclude any activities relating to the manufacture of the Product.

1.34 “Commercialization Plan” has the meaning set forth in Section 6.2(a).

1.35 “Conditional Approval” means approval by the EMA of the DAA filed by Allos and validated by the EMA on December 15, 2010, including any amendments thereof, which approval shall be received no later than [*].

1.36 “Conducting Party” has the meaning set forth in Section 4.4(c)(i).

1.37 “Confidential Information” of a Party means any and all Information of such Party or its Affiliates that is disclosed by such Party or its Affiliates to the other Party or its Affiliates under this Agreement or the Supply Agreement, whether in oral, written, graphic, or electronic form.

1.38 “Consent” means the consent and agreement among Allos, the PDX Licensor and Mundipharma, dated of even date herewith.

1.39 “Control” means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right, and in each case, has the ability to grant to the other Party access, a license or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.40 “CTCL” means cutaneous T-cell lymphoma.
1.41 “Current Third Party Manufacturer” means [*] (each as defined in the Supply Agreement).

1.42 “Default Notice” has the meaning set forth in Section 12.2.

1.43 “Develop” or “Development” means all activities relating to preparing and conducting non-clinical studies, clinical studies, and regulatory activities (e.g., preparation of regulatory applications) that are necessary or useful to obtain and maintain Drug Approval of the Product.

1.44 “Development Cost Differential” has the meaning set forth in Section 4.5.

1.45 “Development Plan” has the meaning set forth in Section 4.2(a).

1.46 “Dollars” means U.S. dollars, and “$” shall be interpreted accordingly.

1.47 “Drug Approval” means an approval granted by the appropriate Regulatory Authority to market the Product in the Field in any particular jurisdiction in the Licensed Territory; provided, “Drug Approval” shall include any and all marketing authorizations in the EU but exclude any and all Pricing Approvals and Reimbursement Approvals.

1.48 “Drug Approval Application” or “DAA” means an application to the appropriate Regulatory Authority for approval to market the Product in the Field in any particular jurisdiction in the Licensed Territory; provided, “Drug Approval Application” shall include any and all marketing authorization applications in the EU but exclude any and all applications for Pricing Approvals and Reimbursement Approvals.

1.49 “eCTD” has the meaning set forth in Section 5.1(c).

1.50 “EEA” means the EU plus Iceland, Liechtenstein and Norway.

1.51 “EMA” means the European Medicines Agency or any successor entity.

1.52 “EMA Approval Additional Studies” has the meaning set forth in Section 4.3.

1.53 “EU” or “European Union” means the European Union member states as then constituted; provided, as of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

1.54 “EU Major Market Country” means any of the following countries: [*].

1.55 “EU Pediatric Investigation Plan” means a research and development program aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorized to treat the pediatric (i.e., between birth and 18 years) population.

1.56 “Executive Officers” has the meaning set forth in Section 3.1(d).

1.57 “Existing Studies” has the meaning set forth in Section 4.2(b).

1.58 “Expert” has the meaning set forth in Section 6.6(b).

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.


1.60 “FDA” means the U.S. Food and Drug Administration or any successor entity.

1.61 “Field” means the diagnosis or treatment of [*].

1.62 [*] has the meaning set forth in Section 7.3(b).
1.63 "[ * ]" has the meaning set forth in Section 7.3(d).

1.64 "First Commercial Sale" means, with respect to a particular Product, the first sale to a Third Party of such Product in a given regulatory jurisdiction after Drug Approval has been obtained in such jurisdiction.

1.65 "First Confidentiality Agreement" means the confidentiality agreement between Allos and Mundipharma dated [ * ].

1.66 "[ * ]" has the meaning set forth in Section 7.3(b).

1.67 "[ * ]" has the meaning set forth in Section 7.3(d).

1.68 "First Line PTCL" means treatment of previously undiagnosed PTCL patients or treatment of previously undiagnosed PTCL patients who achieved an objective response following initial treatment with CHOP-based chemotherapy, where "PTCL" for this purpose is defined by the population included in the PDX-017 study or any subsets of such population.

1.69 "First Reimbursable Commercial Sale" means, with respect to a particular Product, the first sale to a Third Party of such Product in a given regulatory jurisdiction after all relevant Regulatory Approvals have been obtained in such jurisdiction.

1.70 "Generic Product" means any pharmaceutical product in a particular regulatory jurisdiction that (a) contains the same active pharmaceutical ingredients as the Product; (b) is bioequivalent to the Product as determined by the applicable Regulatory Authority in such jurisdiction; (c) has one or more Regulatory Authority-approved Indications in such jurisdiction equivalent to the Regulatory Authority-approved Indication for the Product in such jurisdiction (provided that the references to "such jurisdiction" in this subsection (c) means, with respect to Regulatory Authority-approved Indications in the EEA, any one or more country(ies) in the EEA); and (d) is sold in such jurisdiction by a Third Party that is not a Sublicensee of Mundipharma or its Affiliates, and is not otherwise authorized by Mundipharma or any of its Affiliates, Sublicensees or distributors to sell such product.

1.71 "Good Clinical Practices" or "GCP" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Licensed Territory and/or the Allos Territory, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.72 "Good Laboratory Practices" or "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Licensed Territory and/or the Allos Territory, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.73 "Good Manufacturing Practices" or "GMP" means the standards relating to current Good Manufacturing Practices for fine chemicals, API, intermediates, bulk products or finished pharmaceutical products set forth in (i) 21 U.S.C. 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211 and in The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, or (ii) the ICH Guidelines relating to the manufacture of API and finished pharmaceuticals, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.74 "Governmental Authority" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.75 "Health Canada" means the Canadian federal government agency responsible for the administration of, inter alia, the Canada Food and Drugs Act, or any successor agency with responsibilities comparable to those of Health Canada.

1.76 "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.77 "ICH Guidelines" means the guidelines of the ICH.

1.78 "Incremental Study" has the meaning set forth in Section 4.4(c)(i).
1.79 “Indemnified Party” has the meaning set forth in Section 10.4.

1.80 “Indemnifying Party” has the meaning set forth in Section 10.4.

1.81 “Indication” means any disease or condition that can be diagnosed or treated.

1.82 “Information” means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

1.83 “Investigator-Sponsored Study” or “ISS” means a clinical trial on the Product in the Field wherein a Third Party that is not a sublicensee or subcontractor of either Party holds the investigational new drug application or equivalent thereof (if any) for such trial and is solely responsible for all aspects of the trial, including: trial design; ensuring appropriate institutional and regulatory approval; conducting such trial, including responsibility for ensuring appropriate medical safeguards, medical monitoring and medical supervision; analysis and interpretation of the results of such trial; and communication (e.g., publications) of the results of such trial; provided, if either Party has any responsibility for any of the foregoing, then such trial shall not be considered an Investigator-Sponsored Study.

1.84 “JAMS Rules” has the meaning set forth in Section 13.1.

1.85 “Joint Commercialization Committee” or “JCC” has the meaning set forth in Section 3.3.

1.86 “Joint Development Committee” or “JDC” has the meaning set forth in Section 3.2.

1.87 “Joint Development Costs” means all costs reasonably incurred by or on behalf of either Party after the Effective Date, including out-of-pocket costs actually incurred by each Party, [ ], all as calculated in accordance with U.S. generally accepted accounting principles consistently applied or international financial reporting standards, as applicable, that are reasonably and directly allocable to such Party’s performance of its obligations under this Agreement with respect to any Shared Study (other than an Allos Study), to the extent that such costs do not exceed [ ] of the budget therefor as specified in the Development Plan; provided, however, “Joint Development Costs” shall specifically exclude (i) all internal costs, and (ii) any and all costs associated with preparing and filing any and all Regulatory Materials and communicating with any Regulatory Authorities, in each case for the purpose of obtaining and maintaining Regulatory Approval.

1.88 “Joint Inventions” has the meaning set forth in Section 8.1.

1.89 “Joint Manufacturing Committee” or “JMC” has the meaning set forth in Section 3.4.

1.90 “Joint Patents” has the meaning set forth in Section 8.1.

1.91 “Joint Steering Committee” or “JSC” has the meaning set forth in Section 3.1.

1.92 “Knowledge” means, with respect to the Party to which such term is attributed, (i) the actual knowledge of: (a) for Allos: [ ]; and (b) for Mundipharma, the following executives of Mundipharma International Limited, Mundipharma’s Affiliate: [ ]; or (ii) the knowledge that any of the foregoing individuals reasonably should have gained through operating in the ordinary course of business with a level of efforts and resources consistent with the business practices of a similarly sized company with a similarly sized infrastructure to support and carry out its operations.

1.93 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.
1.94 "Lead Indication" means the treatment of adult patients with relapsed or refractory PTCL, where "PTCL" for this purpose is defined by the population included in the "PROPEL" study (PDX-008) or any subset(s) of such population.

1.95 "Letter Agreement" means the letter agreement between Allos and Mundipharma, dated of even date herewith, in respect of (i) the initial Development Plan and (ii) Allos' registered domain names.

1.96 "Licensed Marks" has the meaning set forth in Section 8.9(a).

1.97 "Licensed Territory" means all countries of the world excluding those in the Allos Territory.

1.98 "Licensed Territory Infringement" has the meaning set forth in Section 8.4(a).

1.99 "Major Market Countries" means the [*].

1.100 "Material Impact" means, with respect to a Party, a material adverse impact on the regulatory status or the commercial sales of the Product in such Party's applicable territory.

1.101 "MMCO" means Mundipharma Medical Company, a partnership organized under the laws of Bermuda, and an Affiliate of Mundipharma.

1.102 "Mundipharma-Facilitated ISS" means an ISS that Mundipharma authorizes or facilitates in accordance with Section 4.7.

1.103 "Mundipharma Indemnities" has the meaning set forth in Section 10.1.

1.104 "Mundipharma ISS Technology" means (a) all Information that (i) is necessary or useful for the Development or Commercialization of a Product in the Field, (ii) is Controlled by Mundipharma or its Affiliates during the Term, and (iii) arises from a Mundipharma-Facilitated ISS, and (b) any Patent (other than a Joint Patent) that (x) claims the Product or the API or the manufacture or use in the Field of the Product or the API, (y) is Controlled by Mundipharma or its Affiliates during the Term, and (z) claims an invention arising from a Mundipharma-Facilitated ISS; provided, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate of Mundipharma after the Effective Date due to a Change of Control of Mundipharma, to any extent such Third Party's Information or Patents are Controlled by Mundipharma (or its Acquiror) or any of its other Affiliates and are necessary for the Development or Commercialization of the Product and are utilized in respect of the Product or the API in the Licensed Territory.

1.105 "Mundipharma Know-How" means all Information that (a) is necessary or useful for the Development or Commercialization of a Product in the Field and (b) is Controlled by Mundipharma or its Affiliates during the Term and arises from a Shared Study (including any Incremental Study that becomes an Additional Study upon Allos' exercise of the Opt-In Right under Section 4.4(c)(v)); provided, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate of Mundipharma after the Effective Date due to a Change of Control of Mundipharma, except to the extent such Third Party's Information is Controlled by Mundipharma (or its Acquiror) or any of its other Affiliates and is necessary for the Development or Commercialization of the Product and is utilized in respect of the Product or the API in the Licensed Territory; and provided further that "Mundipharma Know-How" excludes Information arising from any Incremental Study (with respect to which Allos does not exercise its Opt-In Right under Section 4.4(c)(v)) or Investigator-Sponsored Study.

1.106 "Mundipharma Patent" means any Patent (other than a Joint Patent) that (a) claims the Product or the API or the manufacture or use in the Field of the Product or the API and (b) is Controlled by Mundipharma or its Affiliates during the Term and claims an invention arising from a Shared Study (including any Incremental Study that becomes an Additional Study upon Allos' exercise of the Opt-In Right under Section 4.4(c)(v)); provided, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate of Mundipharma after the Effective Date due to a Change of Control of Mundipharma, except to the extent such Third Party's Patents are Controlled by Mundipharma (or its Acquiror) or any of its other Affiliates and are necessary for the Development or Commercialization of the Product and are utilized in respect of the Product or the API in the Licensed Territory; and provided further that "Mundipharma Patent" excludes any Patent that claims an invention arising from any Incremental Study (with respect to which Allos does not exercise its Opt-In Right under Section 4.4(c)(v)) or Investigator-Sponsored Study.

1.107 "Mundipharma Payment-Allos Withholding Tax Action" has the meaning set forth in Section 7.10(c)(ii).

1.108 "Mundipharma Payment-Mundipharma Withholding Tax Action" has the meaning set forth in Section 7.10(c)(i).

1.109 "Mundipharma Share" has the meaning set forth in Section 4.5.

1.110 "Mundipharma Sublicense Agreement" has the meaning set forth in Section 2.1(f)(ii).
1.111 "Mundipharma Technology" means the Mundipharma Know-How, Mundipharma Patents and Mundipharma’s interest in Joint Patents.

1.112 “Net Sales” means, with respect to any Product, the total amount invoiced by Mundipharma, its Affiliates or Sublicensees to each Third Party receiving Product in an arms length transaction, less: (a) [*]; (b) [*]; (c) [*]; and (d) [*]; provided, amounts received by Mundipharma, its Affiliates or Sublicensees for the sale of Product among the Parties, and their Affiliates and sublicensees (including Sublicensees) for resale shall not be included in the computation of Net Sales hereunder.

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For purposes of this definition of “Net Sales”, if Mundipharma, its Affiliate or sublicensee sells a Product in the form of a combination product containing one or more active ingredients in addition to Product, “Net Sales” for such combination product will be calculated by multiplying actual Net Sales thereof by the fraction A/(A+B) where A is the invoice price of the Product if sold separately, and B is the total invoice price of the other active ingredient or ingredients in the combination, if sold separately. If, on a country-by-country basis, the other active ingredient or ingredients in the combination are not sold separately in said country, “Net Sales” shall be calculated by multiplying actual Net Sales thereof by the fraction A/C where A is the invoice price of the Product if sold separately, and C is the invoice price of the combination product. If, on a country-by-country basis, the Product is not sold separately in said country, “Net Sales” shall be determined by the Parties in good faith on the basis of the fair market value of the Product. With respect to any transfer of any Product in a given country for any substantive consideration other than monetary consideration on arms length terms, for purposes of calculating “Net Sales” under this Agreement, such Product shall be deemed to be sold exclusively for money at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only de minimus cash sales in such country, at the fair market value as determined by comparable markets).

1.113 “New Compound” means (i) any active pharmaceutical ingredient other than the API, or (ii) any pharmaceutical product containing an active pharmaceutical ingredient other than the API.

1.114 “New Form” means a form of API (as defined in this Agreement) or Product that is different from API (as defined in the Supply Agreement) or Bulk Product, respectively.

1.115 “Non-Breaching Party” has the meaning set forth in Section 12.2.

1.116 “Non-Conducting Party” has the meaning set forth in Section 4.4(c)(i).

1.117 “Non-Governmental Authority” means any public body (including the National Institute of Clinical Excellence and the Scottish Medicines Consortium in the U.K.; the Institute for Quality and Efficiency in Healthcare in Germany; the Technical Scientific Commission in Italy; the Directorate of Pharmacy and Healthcare Products in Spain; and the National Union of Health Insurance Funds and the National Authority of Health in France) or non-Governmental Authority (including “Sick Funds” in Germany) with the authority to control, approve, recommend or otherwise determine pricing and reimbursement of pharmaceutical products, including those with authority to enter into risk sharing schemes and/or to impose retroactive price reductions, discounts, or rebates.

1.118 “Non-Oncology Indication” means any Indication that is not an Oncology Indication.

1.119 “Oncology Indication” means any Indication in the field of oncology, as defined by the American Cancer Society, including all Indications listed in Exhibit A.

1.120 “Opt-In Estimate” has the meaning set forth in Section 4.4(c)(v).

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1.121 “Opt-In Option Date” has the meaning set forth in Section 4.4(c)(v).

1.122 “Opt-In Payment” has the meaning set forth in Section 4.4(c)(v).

1.123 “Opt-In Right” has the meaning set forth in Section 4.4(c)(v).

1.124 “Other Committees” has the meaning set forth in Section 3.1(a)(viii).
1.125 “Patents” means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) any other patent application claiming priority to any of the foregoing anywhere in the world; and (d) extension, renewal or restoration of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

1.126 “Payee” has the meaning set forth in Section 7.7.

1.127 “PDX Breach” has the meaning set forth in Section 12.4(c)(i).

1.128 “PDX License Agreement” means the License Agreement dated as of December 23, 2002 by and among Allos, SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute, as amended.

1.129 “PDX Licensor” means, collectively, SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute, and any successors thereto.

1.130 “PDX Patents” means the Allos Patents licensed by Allos from the PDX Licensor under the PDX License Agreement, which Patents in existence on the Effective Date are shown in Schedule 1 with the PDX Licensor listed as the “Registered Proprietor”.

1.131 “Pediatric Studies” has the meaning set forth in Section 4.2(b).

1.132 “Percentage Market Penetration” means the percentage obtained by dividing [*] by the [*].

1.133 “Percentage Price Reduction” means the percentage by which [*] is reduced, as compared to the [*] as a result of (x) [*] or (y) [*].

1.134 “Pharmacovigilance Agreement” has the meaning set forth in Section 5.7(a).

1.135 “Phase 1 Study” means a human clinical trial of the Product with the endpoint of determining initial tolerance, safety or pharmacokinetic information in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens, as described in 21 C.F.R. § 312.21(a) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

1.136 “Phase 2 Study” means a human clinical trial of the Product, the principal purpose of which is a preliminary determination of safety and efficacy in the target patient population over a range of doses and dose regimens, as described in 21 C.F.R. § 312.21(b) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

1.137 “Pricing Approval” means the governmental approval, agreement, determination or decision establishing prices for the Product that can be charged in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price of pharmaceutical products.

1.138 “Primary Agreement” has the meaning set forth in Section 9.2(t).

1.139 “Product” means any pharmaceutical product containing the API, [*], or any improvement made by Allos or Mundipharma to the API, [*] developed by Allos or Mundipharma pursuant to the terms of this Agreement; provided, however, that notwithstanding the foregoing, except as provided in Section 9.4(m), Mundipharma shall have no rights or licenses under this Agreement in or to any New Compound that is Controlled by Allos or its Affiliates.

1.140 “Proposed Study” has the meaning set forth in Section 4.4.

1.141 “PSURs” has the meaning set forth in Section 5.1(b).

1.142 “PTCL” means peripheral T-cell lymphoma.

1.143 “Publication” has the meaning set forth in Section 11.3.

1.144 “Reasonably Diligent Efforts” means, with respect to a Party’s obligations under this Agreement, the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices of a similarly sized company [*]; provided, “Reasonably Diligent Efforts” shall (i) [*]; and (ii) require that the Party: (a) [*], (b) [*], and (c) [*]; and provided further, that “Reasonably Diligent Efforts” (i) with respect to each Party, requires that such Party [*] or (ii) [*].
1.145 “Regulatory Approval” means (i) Drug Approval and all other approvals necessary for the commercial sale of the Product in a given country or regulatory jurisdiction; (ii) Pricing Approval (but only in those countries or regulatory jurisdictions where Pricing Approval is required by applicable Law for commercial sale); and (iii) Reimbursement Approval, but only in those countries or regulatory jurisdictions where Reimbursement Approval is required for the price paid for the Product to be reimbursed by a Governmental Authority or a Non-Governmental Authority with the authority to approve reimbursement.

1.146 “Regulatory Authority” means, in a particular country or jurisdiction, any applicable Governmental Authority or Non-Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.147 “Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations, Drug Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize the Product in a particular country or jurisdiction.

1.148 “Regulatory Plan” means a plan regarding the timing and approach to preparing, submitting or reviewing Regulatory Materials and obtaining and maintaining Drug Approval.

1.149 “Reimbursement Approval” means the approval, agreement, determination or decision recommending or approving the Product for use and/or establishing the prices for the Product that can be reimbursed in regulatory jurisdictions where the applicable Governmental Authority or Non-Governmental Authority approves, determines or recommends the reimbursement or use of pharmaceutical products.

1.150 “Related Study” has the meaning set forth in Section 4.4(d).

1.151 “Remedial Action” has the meaning set forth in Section 5.8.

1.152 “Royalty Term” has the meaning set forth in Section 7.4(b).

1.153 “Safety Reason” has the meaning set forth in Section 13.2(a).

1.154 “SEC” has the meaning set forth in Section 11.4(d).

1.155 “[*]” has the meaning set forth in Section 7.3(b).

1.156 “[*]” has the meaning set forth in Section 7.3(d).

1.157 “Second Confidentiality Agreement” means the confidentiality agreement between Allos and Mundipharma Pharmaceuticals Inc. [*].

1.158 “[*]” has the meaning set forth in Section 7.3(b).

1.159 “[*]” has the meaning set forth in Section 7.3(d).

1.160 “Serious Adverse Event” has the meaning set forth in Section 5.7(b).

1.161 “Shared Claims” has the meaning set forth in Section 10.3.

1.162 “Shared Costs” has the meaning set forth in Section 10.3.

1.163 “Shared Study” means any of the Existing Studies (including Allos Studies and Pediatric Studies), EMA Approval Additional Studies or Additional Studies.

1.164 “Sole Inventions” has the meaning set forth in Section 8.1.

1.165 “Sublicense Revenue” means [*], but excluding sums received: (a) [*]; (b) [*]; (c) [*]; (d) [*]; (e) [*]; (f) [*]; or (g) [*]; provided, however, [*] then for purposes of calculating Sublicense Revenue arising from [*].
ARTICLE 2
LICENSES

2.1 Licenses to Mundipharma.

(a) Development License to Mundipharma. Subject to the terms and conditions of this Agreement, Allos hereby grants to Mundipharma an exclusive (even as to Allos except as provided in Section 2.1(e)), milestone-bearing right and license, with the right to sublicense solely as provided in Section 2.1(f), under the Allos Technology and the Allos ISS Technology, to Develop Products in the Field in accordance with the Development Plan and for the purpose of obtaining or maintaining Regulatory Approvals in the Field in the Licensed Territory or otherwise exercising Mundipharma’s rights or performing Mundipharma’s obligations under the Development Plan (including for the purpose of conducting any Additional Study pursuant to Section 4.4(a) or 4.4(b) or proceeding with an Incremental Study pursuant to Section 4.4(c) in the Licensed Territory or the Allos Territory). For clarity, the foregoing license does not include a right for Mundipharma to manufacture or have manufactured Products for use in Development, and Mundipharma’s and its designees’ only rights under the Allos Technology to manufacture or have manufactured Products are as expressly set forth in Section 2.1(c) and in the Supply Agreement. For further clarity, the foregoing license does not include a right for Mundipharma to make or have made any derivatives of the API. If Mundipharma wishes to make any such derivatives, it shall inform Allos in writing and shall refrain from making or having made any such derivatives of the API unless and until it receives Allos’ prior written consent.

(b) Commercial License To Mundipharma. Subject to the terms and conditions of this Agreement, Allos hereby grants to Mundipharma an exclusive (even as to Allos except as provided in Section 2.1(e)), milestone- and royalty-bearing right and license, with the right to sublicense solely as provided in Section 2.1(f), under the Allos Technology and the Allos ISS Technology, to use, sell, offer for sale, import, export, distribute, warehouse, market, promote, apply for and submit applications for Pricing Approval and Reimbursement Approval, and otherwise Commercialize Products in the Field in the Licensed Territory. For clarity, the foregoing license does not include a right for Mundipharma to manufacture or have manufactured Products for use in Commercialization, and Mundipharma’s and its designees’ only rights under the Allos Technology to manufacture or have manufactured Products are as expressly set forth in Section 2.1(c) and in the Supply Agreement.

(c) Manufacturing Licenses.

(i) With Respect to Bulk Product. Subject to the terms and conditions of this Agreement and the Supply Agreement, Allos hereby grants to Mundipharma a non-exclusive, royalty-free limited right and license, with the right to sublicense in accordance with Section 2.1(f) to its Affiliates or, with the prior written consent of Allos to a Third Party manufacturer (which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that with respect to a sublicense to the Current Third Party Manufacturer of Bulk Product, the terms of Section 2.1(f)(i) shall govern), under the Allos Manufacturing Know-How and Allos Patents, to manufacture Bulk Product solely for use in accordance with this Agreement.

(ii) With Respect to API (as defined in the Supply Agreement). Subject to the terms and conditions of this Agreement and the Supply Agreement, Allos hereby grants to Mundipharma a non-exclusive, royalty-free limited right and license, with the right to sublicense in accordance with Section 2.1(f) to its Affiliates or, with the prior written consent of Allos to a Third Party manufacturer (which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that with respect to a sublicense to the Current Third Party Manufacturers of API, the terms of Section 2.1(f)(ii) shall govern), under the Allos Manufacturing Know-How and Allos Patents, to manufacture API (as defined in the Supply Agreement) solely for use in non-clinical studies in accordance with this Agreement and for use by Mundipharma or its Affiliates or permitted Third Party manufacturers in manufacturing Bulk Product in accordance with Section 2.1(c)(i).
(d) PDX License Agreement. The licenses granted to Mundipharma in Sections 2.1(a), 2.1(b) and 2.1(c) include sublicenses under Allos Technology licensed to Allos under the PDX License Agreement. The licenses granted to Mundipharma in Sections 2.1(a), 2.1(b) and 2.1(c) are subject to the license rights and restrictions associated with such rights under the PDX License Agreement, in each case, to the extent applicable to the rights granted to Mundipharma hereunder.

(e) Allos Retained Rights. Notwithstanding the exclusive rights granted to Mundipharma in Sections 2.1(a) and 2.1(b) and without limiting the generality of Section 2.4, Allos retains the right to practice the Allos Technology to: (i) Develop the Product in the Field in accordance with the Development Plan and for the purpose of exercising Allos’ rights or performing Allos’ obligations under the Development Plan (including for the purpose of conducting any Additional Study pursuant to Section 4.4(a) or 4.4(b) or proceeding with an Incremental Study pursuant to Section 4.4(c)) in the Licensed Territory or the Allos Territory; (ii) Develop the Product for the purpose of obtaining or maintaining Regulatory Approval in the Allos Territory; (iii) use, sell, offer for sale, import, export, distribute, warehouse, market, promote, apply for and submit applications for Pricing Approval and Reimbursement Approval, and otherwise Commercialize Products in the Field in the Allos Territory; (iv) manufacture or have manufactured Products anywhere in the world; and (v) practice and license the Allos Technology in the Field in the Allos Territory.

(f) Sublicense Rights.

(i) Mundipharma shall have the right to grant sublicenses (i) of the licenses granted in Sections 2.1(a), 2.1(b) and 2.1(c) or (ii) to sell Products in the Licensed Territory in the Field, in each case, without the prior approval of Allos, only to (A) its Affiliates, provided that such sublicense shall automatically terminate if such person, corporation, partnership or entity ceases to be an Affiliate of Mundipharma, and (B) Third Party subcontractors that are performing part of Mundipharma’s obligations under this Agreement (excluding any Third Party manufacturers), and in each case provided that Mundipharma shall at all times sell, offer for sale, import, export and otherwise Commercialize the Product in Mundipharma’s or its Affiliate’s name. Mundipharma shall not grant any sublicenses (i) of the licenses granted in Sections 2.1(a), 2.1(b) and 2.1(c), or (ii) any rights to sell the Product in the Field in the Licensed Territory, to any Third Party (including any Third Party manufacturer but excluding any non-manufacturing Third Party subcontractors as permitted in the preceding sentence) without the prior approval of Allos, which approval shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, the Parties agree it would be reasonable for Allos to withhold consent [ * ], unless, at the time such consent is requested, (i) [ * ], and (ii) [ * ]. Mundipharma shall be solely responsible for all of its Sublicensees’, subcontractors’, agents’ and distributors’ activities and any and all failures by its Sublicensees, subcontractors, agents or distributors to comply with the terms of this Agreement.

(ii) Mundipharma shall, within [ * ] after granting any sublicense under Sections 2.1(a), 2.1(b) or 2.1(c) above, or rights to sell the Product in the Field in the Licensed Territory to a Third Party, notify Allos of the grant of such sublicense to a Third Party and provide Allos with a true and complete copy of the agreement (a “Mundipharma Sublicense Agreement”) between Mundipharma and such Third Party (the “Sublicensee”), pursuant to which such sublicense or rights were granted. Each Mundipharma Sublicense Agreement shall be consistent with the terms and conditions of this Agreement and shall include the following additional terms and conditions:

(A) No Mundipharma Sublicense Agreement shall obligate (or purport to obligate) Allos without Allos’ express written consent;

(B) the Sublicensee shall provide Mundipharma with all Information, Regulatory Materials and other documentation necessary for Mundipharma to comply with its obligations under this Agreement, including payment and reporting obligations hereunder, and shall include audit provisions substantially similar to those contained in this Agreement;

(C) the Sublicensee shall be bound by non-use and non-disclosure obligations no less stringent than those set forth in this Agreement;

(D) the Sublicensee shall not have any right to grant sublicenses to the Allos Technology or the Mundipharma Technology;

(E) the Sublicensee shall not have any right to prosecute or maintain any Allos Patents, Joint Patents or Mundipharma Patents; and
Mundipharma shall own and control all information and patents relating to the product or the API made and all regulatory materials prepared or filed by the sublicensee in the course of conducting its activities under the Mundipharma sublicense agreement.

With respect to any Mundipharma sublicense agreement that includes a sublicense under Allos Technology licensed to Allos under the PDX License Agreement:

(A) Allos shall be permitted to provide SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute, with a copy of such Mundipharma sublicense agreement; and

(B) the sublicensee’s rights shall be subject to the license rights and restrictions associated with such rights under the PDX License Agreement, in each case to the extent applicable to the rights granted to the sublicensee.

Mundipharma shall pay to Allos [*] of all sublicense revenue within [*] after the end of the calendar quarter in which Mundipharma receives such sublicense revenue from a third party.

Limited incremental study license to Mundipharma. Subject to the terms and conditions of this agreement, Mundipharma hereby grants to Mundipharma a non-exclusive, fully paid, royalty-free limited right and license under any patent controlled by Mundipharma during the term that claims the product or the API or the manufacture or use in the field of the product or the API (other than an Allos patent, joint patent or patent within the Allos ISS technology), to the extent necessary for the development of product in accordance with the development plan (in the Allos territory or the licensed territory) or for the commercialization of the product in the field in the licensed territory.

2.2 License to Allos.

(a) Subject to the terms and conditions of this agreement, Mundipharma hereby grants to Allos (i) a co-exclusive, fully paid, royalty-free right and license (with the right

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to grant sublicenses) under the Mundipharma Technology and the Mundipharma ISS Technology, to develop products in the field in accordance with the development plan or to otherwise exercise Allos’ rights or perform Allos’ obligations under the development plan (including for the purpose of conducting any additional study pursuant to section 4.4(a) or 4.4(b) or proceeding with an incremental study pursuant to section 4.4(c) in the licensed territory or the Allos territory); and (ii) an exclusive (even as to Mundipharma), fully paid, royalty-free right and license (with the right to grant sublicenses), under the Mundipharma Technology and the Mundipharma ISS Technology, to (A) develop products in the field for the purpose of obtaining or maintaining regulatory approval in the Allos territory, and (B) use, sell, offer for sale, import, distribute, warehouse, market, promote, apply for and submit applications for pricing approval and reimbursement approval, and otherwise commercialize products in the field in the Allos territory. Notwithstanding the exclusive rights granted to Allos in this section 2.2 and without limiting the generality of section 2.4, Mundipharma retains the right to practice the Mundipharma Technology for the purpose of performing Mundipharma’s obligations under the development plan with respect to shared studies.

(b) Limited incremental study license to Allos. Subject to the terms and conditions of this agreement, Mundipharma hereby grants to Allos a non-exclusive, fully paid, royalty-free limited right and license under any patent controlled by Mundipharma that claims the product or the API or the manufacture or use in the field of the product or the API (other than a Mundipharma patent, joint patent or patent within the Mundipharma ISS technology) to the extent necessary for the development of product in accordance with the development plan (in the Allos territory or the licensed territory) or for the commercialization of the product in the field in the Allos territory.

(c) Manufacturing license to Allos. Subject to the terms and conditions of this agreement, Mundipharma hereby grants to Allos a non-exclusive, fully paid, royalty-free, irrevocable limited right and license (with the right to grant sublicenses), under information or inventions made, conceived, obtained or generated by or on behalf of Mundipharma or any of its affiliates or third party manufacturers in the course of manufacturing product or API or any components thereof and any patents claiming such information or invention, to manufacture and have manufactured API and product. Mundipharma shall use reasonable best efforts to promptly disclose to Allos all information and inventions made, conceived, obtained or generated by or on behalf of Mundipharma or any of its affiliates or third party manufacturers in the course of manufacturing product or API or any components thereof.

2.3 Negative covenant. Mundipharma covenants that it will not, and will not permit any of its affiliates or sublicensees to, use or practice any Allos technology or Allos ISS technology outside the scope of the license granted to it under sections 2.1(a), 2.1(b) and 2.1(c). Allos covenants that it will not, and will not permit any of its affiliates or sublicensees to, use or practice any Mundipharma technology or Mundipharma ISS technology outside the scope of the licenses granted to it under section 2.2.

2.4 No implied licenses. Except as explicitly set forth in this agreement, neither party shall be deemed by estoppel or implication to have granted the other party any license or other right to any intellectual property of such party.
ARTICLE 3
GOVERNANCE

3.1 Joint Steering Committee.

(a) Formation and Role. Within [ * ] after the Effective Date, the Parties shall establish a joint steering committee (the “Joint Steering Committee” or “JSC”) for the overall coordination and oversight of the Parties’ activities under this Agreement. The role of the JSC shall be:

(i) to review, discuss and approve the overall strategy for the Development and Drug Approval of the Product in the Field in the Licensed Territory;

(ii) to review and discuss the overall performance of the Parties pursuant to this Agreement and to compare such performance to the objectives outlined in the Development Plan and to the diligence obligations set forth in Section 4.6;

(iii) to review, discuss and approve any amendments to the Development Plan proposed by the JDC (including the Regulatory Plan to be added to the Development Plan after the Effective Date);

(iv) to review and discuss the Commercialization Plan and any amendments to the Commercialization Plan proposed by the JCC;

(v) to review and discuss overall strategy for Pricing Approval and Reimbursement Approval of the Product in the Field in the Licensed Territory;

(vi) to discuss the Parties’ activities with respect to the Product in the Field in the Licensed Territory in conjunction with Allos’ and its licensees’ activities with respect to the Product in the Field in the Allos Territory;

(vii) to review any [ * ] after receipt of Regulatory Approval;

(viii) to direct and oversee the JDC, JCC, JMC and any other operating committee (the “Other Committees”) established by the JSC, on all significant issues that fall within the purview of such committees;

(ix) to appoint Other Committees, consisting of equal numbers of appropriately qualified members appointed by each Party, from time to time as it deems fit;

(x) to attempt to resolve, in a timely manner, issues presented to it by, and disputes within, the JDC, JCC, JMC and Other Committees; and

(xi) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing.

The JSC shall have only the powers expressly assigned to it in this Section 3.1 and elsewhere in this Agreement. The JSC shall have no power to interpret, amend, modify, or waive compliance with this Agreement.

(b) Members. Each Party shall initially appoint two (2) representatives to the JSC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC’s responsibilities. The JSC may change its size from time to time by mutual consent of its members and each Party may replace its representatives at any time upon written notice to the other Party; provided, however, that the JSC will at all times consist of equal numbers of members appointed by each Party. In the event a JSC representative from either Party is unable to attend or participate in a meeting of the JSC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting, in its sole discretion. The JSC shall have a chairperson, who shall be elected, on an annual basis, alternatively by Allos or Mundipharma. The initial chairperson shall be selected by Allos. The role of the chairperson shall be to convene and preside at all meetings of the JSC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JSC representatives.
Meetings. The JSC shall meet at least one (1) time per calendar quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) upon at least [ * ] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JSC no later than [ * ] prior to the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JSC may meet in person, by videoconference or by teleconference, provided, however, at least two (2) meetings per calendar year shall be in person at a mutually agreeable location or alternating each meeting between Cambridge, U.K. and Princeton, New Jersey, unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JSC meetings as non-voting observers and/or presenters. The chairperson of the JSC shall be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect and include all material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval within ten (10) business days after each JSC meeting. Such minutes shall be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) business days of receipt.

Decision Making. Actions to be taken by the JSC shall be taken only following unanimous vote, with each Party having one (1) vote representing the views of its members. If the JSC fails to reach unanimous agreement on a matter before it for decision for a period in excess of [ * ], either Party may submit the matter in writing to the other, and the Parties shall refer such dispute to the Chief Executive Officer of Allos and the Regional Director, Europe of Mundipharma International Limited, an Affiliate of Mundipharma (or their respective designees) for resolution in accordance with the decision-making procedures described in Section 13.2; provided, however, that the following disputes shall not be submitted to the Executive Officers for resolution and instead shall be decided as follows: (i) for any dispute regarding [ * ], the JSC members for [ * ]; (ii) for any dispute regarding [ * ], the JSC members for [ * ]; and (iii) for any dispute regarding [ * ].

3.2 Joint Development Committee.

(a) Formation and Role. Within [ * ] after the Effective Date, the Parties shall establish a joint development committee (the "Joint Development Committee" or "JDC") that will be responsible for overseeing the Development of the Product in the Field. The role of the JDC shall be:

(i) to oversee the Development of the Product in the Field;

(ii) to prepare amendments to the Development Plan, including the budget for each Development activity and the design of each clinical trial or other study included or proposed to be included in the Development Plan, for review and approval by the JSC, the first amendment of which shall be to add a Regulatory Plan created by the JDC;

(iii) to agree on the requirements for Drug Approval in the Licensed Territory;

(iv) to establish general guidelines for Investigator-Sponsored Studies with respect to a Product in the Field which, if complied with by a particular ISS, will allow a Party to authorize or facilitate such ISS on prior notice to the JDC but without the need for obtaining the other Party’s approval;

(v) to review any disputes between the Parties regarding a potential Material Impact of an ISS that does not comply with the general guidelines established by the JDC;

(vi) to review, discuss and coordinate the Parties’ scientific presentation and publication strategy relating to Products in the Field;

(vii) to discuss Development activities in the Field between the Licensed Territory and the Allos Territory;

(viii) to facilitate the flow of Information between the Parties with respect to the Development of, and obtaining Drug Approval for, Products in the Field; and

(ix) to perform such other functions as may be appropriate to further the purposes of this Agreement, with respect to the Development of the Product in the Field, as directed by the JSC.

(b) Members. Each Party shall initially appoint three (3) representatives to the JDC, each of whom will be an officer or employee of such Party having sufficient seniority.
3.3 Joint Commercialization Committee.

(a) Formation and Role. Within [*] after the Effective Date, the Parties shall establish a joint commercialization committee (the “Joint Commercialization Committee” or “JCC”) that will be responsible for overseeing the Commercialization of the Product in the Field in the Licensed Territory. The role of the JCC shall be:

(i) to discuss the Parties’ respective Commercialization activities in and as between the Licensed Territory and the Allos Territory;

(ii) to review and comment upon the Commercialization Plan submitted by Mundipharma, as well as any amendments thereto submitted by Mundipharma, and to submit such Commercialization Plan or amendment thereto to the JSC for review and discussion;

(iii) to oversee implementation of the Commercialization Plan;

(iv) to review and discuss overall strategy for Pricing Approval and Reimbursement Approval of the Product in the Field in the Licensed Territory;

(v) to review, discuss and coordinate the Parties’ attendance, Product messaging and presentations (including “poster-board” presentations and industry booths) at international seminars and conferences at which the Product is being discussed; and

(vi) to perform such other functions as appropriate to further the purposes of this Agreement with respect to the Commercialization of the Product, as directed by the JSC.

(b) Members. Each Party shall initially appoint three (3) representatives to the JCC, each of whom will be an officer or employee of such Party having sufficient seniority within the applicable Party to make decisions arising within the scope of the JCC’s responsibilities. The JCC may change its size from time to time by mutual consent of its members and each Party may replace its representatives at any time upon written notice to the other Party. In the event a JCC representative from either Party is unable to attend or participate in a meeting of the JCC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting, in its sole discretion. The JCC shall have a chairperson, who shall be elected, on an annual basis, alternatively by Allos or Mundipharma. The initial chairperson shall be selected by Allos. The role of the chairperson shall be to convene and preside at all meetings of the JCC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JCC representatives.

(c) Meetings. The JCC shall meet at least one (1) time per calendar quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JCC (by videoconference or teleconference) upon at least [*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JCC no later than [*] prior to the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JCC may meet in person, by videoconference or by teleconference, provided, however, at least two (2) meetings per calendar year shall be in person at a mutually agreeable location or alternating each meeting between Cambridge, U.K. and Princeton, New Jersey, unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JCC meetings as non-voting observers and/or presenters. The chairperson of the JCC shall be responsible for preparing reasonably detailed written minutes of all JCC meetings that reflect and include all material decisions made at such meetings. The JCC chairperson shall send draft meeting minutes to each member of the JCC for review and approval within ten (10) business days after each JCC meeting. Such minutes shall be deemed approved unless one or more members of the JCC objects to the accuracy of such minutes within ten (10) business days of receipt.

(d) Decision Making. Actions to be taken by the JCC shall be taken only following unanimous vote, with each Party having one (1) vote representing the views of its members. If the JCC fails to reach unanimous agreement on a matter before it for decision for a period in excess of [*] from the date first presented to the JDC in writing, the matter shall be referred promptly to the JSC for timely resolution.

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within the applicable Party to make decisions arising within the scope of the JDC’s responsibilities. The JDC may change its size from time to time by mutual consent of its members and each Party may replace its representatives at any time upon written notice to the other Party. In the event a JDC representative from either Party is unable to attend or participate in a meeting of the JDC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting, in its sole discretion. The JDC shall have a chairperson, who shall be elected, on an annual basis, alternatively by Allos or Mundipharma. The initial chairperson shall be

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The role of the chairperson shall be to convene and preside at all meetings of the JDC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JDC representatives.

(c) Meetings. The JDC shall meet at least one (1) time per calendar quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) upon at least [*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JDC no later than [*] prior to the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JDC may meet in person, by videoconference or by teleconference, provided, however, at least two (2) meetings per calendar year shall be in person at a mutually agreeable location or alternating each meeting between Cambridge, U.K. and Princeton, New Jersey, unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JDC meetings as non-voting observers and/or presenters. The chairperson of the JDC shall be responsible for preparing reasonably detailed written minutes of all JDC meetings that reflect and include all material decisions made at such meetings. The JDC chairperson shall send draft meeting minutes to each member of the JDC for review and approval within ten (10) business days after each JDC meeting. Such minutes shall be deemed approved unless one or more members of the JDC objects to the accuracy of such minutes within ten (10) business days of receipt.

(d) Decision Making. Actions to be taken by the JDC shall be taken only following unanimous vote, with each Party having one (1) vote representing the views of its members. If the JDC fails to reach unanimous agreement on a matter before it for decision for a period in excess of [*] from the date first presented to the JDC in writing, the matter shall be referred promptly to the JSC for timely resolution.

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within the applicable Party to make decisions arising within the scope of the JDC’s responsibilities. The JDC may change its size from time to time by mutual consent of its members and each Party may replace its representatives at any time upon written notice to the other Party. In the event a JDC representative from either Party is unable to attend or participate in a meeting of the JDC, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting, in its sole discretion. The JDC shall have a chairperson, who shall be elected, on an annual basis, alternatively by Allos or Mundipharma. The initial chairperson shall be
selected by Mundipharma. The role of the chairperson shall be to convene and preside at all meetings of the JCC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JCC representatives.

(c) Meetings. The JCC shall meet at least one (1) time per calendar quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JCC (by videoconference or teleconference) upon at least [ * ] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JCC no later than [ * ] prior to the special meeting with materials reasonably adequate to enable an informed decision to be made by its members. The JCC may meet in person, by videoconference or by teleconference, provided, however, at least two (2) meetings per calendar year shall be in person at a mutually agreeable location or alternating each meeting between Cambridge, U.K. and Princeton, New Jersey, unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend JCC meetings as non-voting observers and/or presenters. The chairperson of the JCC shall be responsible for preparing reasonably detailed written minutes of all JCC meetings that reflect and include all material decisions made at such meetings. The JCC chairperson shall send draft meeting minutes to each member of the JCC for review and approval within ten (10) business days after each JCC meeting. Such minutes shall be deemed approved unless one or more members of the JCC objects to the accuracy of such minutes within ten (10) business days of receipt.

(d) Decision Making. Actions to be taken by the JCC shall be taken only following unanimous vote, with each Party having one (1) vote representing the views of its members. If the JCC fails to reach unanimous agreement on a matter before it for decision for a period in excess of [ * ] from the date first presented to the JCC in writing, the matter shall be referred promptly to the JSC for timely resolution.

3.4 Joint Manufacturing Committee. A joint manufacturing committee (the “Joint Manufacturing Committee” or “JMC”) will be established pursuant to the Supply Agreement. The roles and responsibilities of the JMC shall be as specified in the Supply Agreement.

3.5 Good Faith. In conducting themselves on any committees, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use Reasonably Diligent Efforts to reach consensus on all matters before them. In exercising any decision-making authority granted to it under this Article 3, each Party shall conduct its discussions in good faith. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of their respective Affiliates shall be required to take, or shall be penalized for not taking, any action that is not in compliance with such Party’s ethical business practices and policies or that such Party reasonably believes is in compliance with applicable Laws.

3.6 Scope of Governance. The Parties agree not to share or discuss any strategic or commercially sensitive information beyond the scope of the collaboration contemplated by this Agreement.

ARTICLE 4

PRODUCT DEVELOPMENT

4.1 Overview. The Parties desire and intend to collaborate with respect to the Development of the Product in the Field, as and to the extent set forth in this Agreement. As described in more detail in this Article 4 (with respect to the non-clinical and clinical aspects of Development) and Article 5 (with respect to the regulatory aspects of Development), the Parties have already agreed that certain Development activities for the Product in the Field will be jointly funded and others will be solely funded by Allos. The Parties have also agreed upon a mechanism for proposing new studies in the Field and determining whether the Parties wish to jointly fund such studies or if one of the Parties may conduct such study without funding from the other Party.
obtain Regulatory Approval in the Field in each country in the Licensed Territory (such timeline, the “Regulatory Plan”). For each Development activity specified in the Development Plan, the Development Plan shall specify the Party that is responsible for such activity, the timeline for initiating and completing such activity, and the budget for such activity. For each clinical trial specified in the Development Plan, the Development Plan shall specify the planned accrual for such trial, the sites at which the trial will be conducted and the lead investigator(s) for such trial.

(b) Initial Development Plan. As of the Effective Date, the Parties have agreed upon an initial Development Plan, which is set forth in the Letter Agreement. The studies set forth in Exhibit 1 to the initial Development Plan (the “Existing Studies”) include: (i) studies that are being conducted by or on behalf of Allos as of the Effective Date; (ii) activities that have not been initiated as of the Effective Date but are needed to generate Information that is required by the FDA as a condition of the Product’s Regulatory Approval in the U.S. for the Lead Indication; (iii) certain medical affairs, and clinical and non-clinical studies that are identified in Exhibit 1 to the initial Development Plan as “Allos Studies”; and (iv) those pediatric studies (and associated preclinical and CMC requirements) required in Exhibit 1 to the initial Development Plan as “Pediatric Studies”). The initial Development Plan identifies the Party with operational responsibility for the activities that form a part of the Existing Studies. Allos shall be solely responsible for timely conducting the Allos Studies and for all costs incurred in the course of conducting the Allos Studies. The Parties shall share the costs of all other Existing Studies as specified in Section 4.5.

(c) Amendments.

(i) The JDC shall periodically (including at the specific times specified in this Section 4.2(c)) review, and, as required, prepare an amendment to the then-current Development Plan, for review, comment and approval by the JSC. Such amended Development Plan shall reflect any changes (including additions) to the Development of the Product in the Field. Once approved by the JSC, the amended Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval.

(ii) Within [*] after the Effective Date, the JDC shall prepare and submit to the JSC for its review, comment and approval, an amendment to the Development Plan that adds the Regulatory Plan to the Development Plan.

(iii) If EMA notifies either Party that any of the Pediatric Studies are not required by the EMA with respect to the Product in the Field or takes other action that results in any of the Pediatric Studies not being required by the EMA with respect to the Product in the Field, the JDC shall promptly prepare and submit to the JSC for its review, comment and

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approval, an amendment to the Development Plan that removes such Pediatric Studies from the Development Plan.

(iv) Promptly after the Parties agree to conduct an Additional Study pursuant to Section 4.4(a) or 4.4(b), or a Party decides to proceed with an Incremental Study pursuant to Section 4.4(c), the JDC shall prepare and submit to the JSC for its review, comment and approval, an amendment to the Development Plan that adds such Additional Study or Incremental Study to the Development Plan.

(v) In addition to the foregoing, no later than June 30th of each calendar year during the Term, starting with 2012, and more frequently at the discretion of the JDC, the JDC shall determine if an amendment is needed to the then-current Development Plan and, if appropriate, shall prepare and submit to the JSC for its review, comment and approval, such amendment to the Development Plan.

(d) Performance. Each Party shall use Reasonably Diligent Efforts to conduct the Development activities allocated to such Party in the Development Plan in a timely and effective manner. Each Party shall conduct its activities under the Development Plan in a good scientific manner and comply in all material respects with all applicable Laws.

4.3 EMA Approval Additional Studies. If the EMA notifies either Party that any clinical studies, in addition to the studies included in the DAA filed by Allos and validated by the EMA on December 15, 2010, and the Existing Studies, are required to obtain, or are a condition of obtaining, Regulatory Approval of the Product by the EMA for the Lead Indication, then such studies will be deemed “EMA Approval Additional Studies” and promptly added to the Development Plan, by amendment in accordance with Section 4.2(c). Unless the Parties agree otherwise in writing, Mundipharma shall be responsible for conducting all EMA Approval Additional Studies and the Parties shall share the costs of such studies as specified in Section 4.5.

4.4 Future Development Activities. If either Party wishes to conduct and/or fund any additional Development activities in the Field (including company-sponsored studies to explore the utility of the Product in the Field and/or to expand the label of the Product in such Party’s territory to include additional Indications, but excluding Investigator-Sponsored Studies, and also including testing one or more New Forms) that are not already set forth in the Development Plan and are not EMA Approval Additional Studies (each of the foregoing activities, a “Proposed Study”), the proposing Party shall present to the other Party’s representatives on the JDC the proposed design and timeline for such Proposed Study and the proposed budget for such Proposed Study. The JDC shall discuss such Proposed Study at its next meeting, whether regularly scheduled or specially requested under Section 3.2(c), and the proposing Party shall provide, within [*] after such JDC meeting (or such longer period of time

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(a) Additional Studies in Oncology Indications. If within [*] after the JDC meeting at which a particular Proposed Study in an Oncology Indication (including a Proposed Study for a New Form that is intended for use in an Oncology Indication) is discussed (or such longer period of time as agreed upon in writing by the Parties), the JDC shall prepare a draft amendment to the Development Plan that would add such Proposed Study to the Development Plan (without specifying if such Proposed Study would be an Additional Study or an Incremental Study) and shall submit such draft amendment to the JSC for review and approval. Prior to the first JSC meeting at which such proposed amendment would be discussed, the proposing Party's representatives to the JSC shall submit to the JDC, for its review and approval, a good faith, commercially reasonable (given the facts and circumstances at the time, including the commercial potential of the Product in the Oncology Indication of the Proposed Study), proposal for milestone payments that, if such Proposed Study were to become an Additional Study, would be paid by Mundipharma to Allos upon (i) the [*], (ii) the [*], (iii) the [*], and (iv) the [*]; provided that the additional agreed-upon milestone payments for such Oncology Indication contemplated in this subsection shall apply only to additional Oncology Indications and not to New Forms (including a Proposed Study for a New Form that is intended for use in an Oncology Indication) is discussed (or such longer period of time as agreed upon in writing by the Parties) (i) the other Party notifies the proposing Party in writing that the other Party wishes to cooperate in such Proposed Study on the terms (including design, budget and timeline) proposed by the proposing Party or (ii) the Parties agree in writing upon the terms (including design, budget and timeline) under which they will cooperate in such Proposed Study, then it will be deemed an “Additional Study” and the Development Plan shall be amended pursuant to Section 4.2(c) to include such Additional Study and the Parties shall have the diligence obligations with respect to such Additional Study as provided in Section 4.2(d). The Parties shall share all Joint Development Costs incurred to conduct such Additional Study in accordance with the applicable budget and in the proportions set forth in Section 4.5. All Information resulting from such Additional Study will be available for use by each Party with respect to the Development and Commercialization of the Product in the Field in its respective territory in accordance with the licenses and rights granted or retained under Article 2 of this Agreement.

(b) Additional Studies in Non-Oncology Indications. Within [*] after the JDC meeting at which a particular Proposed Study in a Non-Oncology Indication (including a Proposed Study for a New Form that is intended for use in a Non-Oncology Indication) is discussed (or such longer period of time as agreed upon in writing by the Parties), the JDC shall prepare a draft amendment to the Development Plan that would add such Proposed Study to the Development Plan (without specifying if such Proposed Study would be an Additional Study or an Incremental Study) and shall submit such draft amendment to the JSC for review and approval. Prior to the first JSC meeting at which such proposed amendment would be discussed, the proposing Party's representatives to the JSC shall submit to the JDC, for its review and approval, a good faith, commercially reasonable (given the facts and circumstances at the time, including the commercial potential of the Product in the Non-Oncology Indication of the Proposed Study in [*]) proposal for milestone payments that, if such Proposed Study were to become an Additional Study, would be paid by Mundipharma to Allos upon (i) the [*], (ii) the [*], (iii) the [*], and (iv) the [*]; provided that the additional agreed-upon milestone payments for such Non-Oncology Indication contemplated in this subsection shall apply only to additional Non-Oncology Indications and not to New Forms (including a Proposed Study for a New Form that is intended for use in a Non-Oncology Indication for which such milestones are payable). If, within [*] after the JSC meeting at which a particular Proposed Study in a Non-Oncology Indication is discussed (or such longer period of time as agreed upon in writing by the Parties), the JSC decides that the Parties will cooperate in such Proposed Study upon agreed-upon terms (including design, timeline, budget and milestone payments), then such Proposed Study will be deemed an Additional Study, the Development Plan shall be amended pursuant to Section 4.2(c) to include such Additional Study, Section 7.3 of this Agreement will be amended to include the agreed-upon milestone payments for such Non-Oncology Indication, and the Parties shall have the diligence obligations with respect to such Additional Study as provided in Section 4.2(d). The Parties shall share all Joint Development Costs incurred to conduct such Additional Study in accordance with the applicable budget and in the proportions set forth in Section 4.5. All Information resulting from such Additional Study will be available for use by each Party with respect to the Development and Commercialization of the Product in the Field in its respective territory in accordance with the licenses and rights granted or retained under Article 2 of this Agreement.

(c) Incremental Studies.

(i) If all information reasonably requested by the non-proposing Party has been provided by the proposing Party and (A) by the [*] after the JDC meeting at which a particular Proposed Study in an Oncology Indication (including a Proposed Study for a New Form that is intended for use in an Oncology Indication) is discussed (or such longer period of time as agreed upon in writing by the Parties) under Section 4.4(a): (x) (1) the other Party has not notified the proposing Party in writing that the other Party wishes to cooperate in such Proposed Study on the terms (including design, budget and timeline) proposed by the proposing Party, or (2) the Parties have not agreed in writing upon the terms (including design, budget and timeline) under which they will cooperate in such Proposed Study, and (y) the other Party has not notified the proposing Party that it believes that such Proposed Study is substantially likely to create a Material Impact; or (B) by the [*] after the JSC meeting at which a particular Proposed Study in a Non-Oncology Indication (including a Proposed Study for a New Form that is intended for use in a Non-Oncology Indication) is discussed (or such longer period of time as agreed upon in writing by the Parties) the JSC does not decide to approve a Proposed Study under Section 4.4(b), then in either case ((A) or (B)), such Proposed Study will be deemed an “Incremental Study”, the proposing Party shall be deemed the “Conducting Party” with respect to such Incremental Study, the other Party shall be deemed the...
Non-Conducting Party with respect to such Incremental Study and, unless the Conducting Party notifies the JDC that it does not wish to proceed with such Incremental Study, the Development Plan shall be amended pursuant to Section 4.2(c) to include such Incremental Study and to specify the Conducting Party as solely responsible for the conduct and costs of such Incremental Study and the Non-Conducting Party shall not be responsible for any costs, including milestones, unless such Non-Conducting Party opts-in to such Incremental Study pursuant to Section 4.4(c)(v). The Conducting Party may proceed with such Incremental Study after such amendment of the Development Plan. If the non-proposing Party believes that such Proposed Study is substantially likely to create a Material Impact and the proposing Party disputes whether such belief is reasonable, the JSC shall discuss and decide whether such belief is reasonable. The Proposed Study shall be deemed an Incremental Study if the JSC decides that the non-proposing Party’s belief is not reasonable. If the JSC agrees that the non-proposing Party’s belief is reasonable, the proposing Party shall not proceed with the Proposed Study. If the JSC cannot agree whether the non-proposing Party’s belief is reasonable, then such dispute shall be handled in accordance with Section 13.2.

(ii) Notwithstanding each Party’s exclusive commercial rights to its respective territory, Mundipharma shall have the right to conduct an Incremental Study in patients in the Allos Territory in accordance with the Development Plan, and Allos shall have the right to conduct an Incremental Study in patients in the Licensed Territory in accordance with the Development Plan.

(iii) The Conducting Party shall promptly inform the JDC of any material changes it wishes to make to an Incremental Study, including the budget therefor, and the Development Plan shall be amended to address them unless the Non-Conducting Party believes that the amendment is substantially likely to have a Material Impact, in which case the JSC shall review such amendment and approve it only if the JSC decides that the Non-Conducting Party’s belief is not reasonable. If the JSC agrees that the Non-Conducting Party’s belief is reasonable, the proposing Party shall proceed without such material changes. If the JSC cannot agree whether the Non-Conducting Party’s belief is reasonable, then such dispute shall be handled in accordance with Section 13.2. The Conducting Party may suspend or terminate an Incremental Study without obtaining approval from the JDC or the JSC if there is a Safety Reason or such suspension or termination is required by a Regulatory Authority or investigational review board; provided, the Conducting Party shall promptly notify the JDC of any such suspension or termination.

(iv) Promptly following the availability of interim data from or completion of an Incremental Study, the Conducting Party shall deliver to the JDC the top-line data summary from such Incremental Study. The Non-Conducting Party will have no rights to use any Information resulting from such Incremental Study in any filings with Regulatory Authorities, for Commercialization in its territory, or otherwise, provided, however, that the Non-Conducting Party may file required safety information with the applicable Regulatory Authorities in its territory in accordance with Section 4.8(b).

(v) Opt-In.

(A) Within [*] of the Conducting Party having obtained final results in an Incremental Study establishing Clinical Proof of Concept, such Conducting Party shall deliver to the Non-Conducting Party the top-line data summary from such Incremental Study (the delivery date of such top-line data summary, the “Opt-In Option Date”), and the Non-Conducting Party with respect to such Incremental Study shall have the right (the “Opt-In Right”) to convert such Incremental Study to an Additional Study by (1) making a payment to the Conducting Party equal to the amount that would have been such Non-Conducting Party’s share (which shall be determined pursuant to Section 4.5) as of the time of the Non-Conducting Party’s exercise of such Opt-In Right of the development costs already incurred by the Conducting Party (which shall be calculated in accordance with Section 1.87, as if such Incremental Study were a Shared Study, but without regard to whether such costs are within [*] of the budget for such Incremental Study as specified in the Development Plan), plus a premium of [*] of such amount (such payment, the “Opt-In Payment”), (2) agreeing with the Conducting Party upon the budget, timeline and allocation of operational responsibility for Development activities, if any, to be performed with respect to such Incremental Study and all Related Studies after the exercise of such Opt-In Right and committing to pay its applicable share (pursuant to Section 4.5) of Joint Development Costs incurred with respect to such Incremental Study and Related Studies after the exercise of such Opt-In Right, and (3) with respect to any Incremental Study that is directed to a Non-Oncology Indication, agreeing with the Conducting Party that Allos shall conduct the Incremental Study in accordance with the Development Plan.

(B) Opt-In for Incremental Study in an Oncology Indication. If the Non-Conducting Party with respect to such Incremental Study in an Oncology Indication is considering exercising its Opt-In Right with respect to such Incremental Study, it shall, no later than [*] after the Opt-In Option Date, notify the Conducting Party in writing and shall request that the Conducting Party provide: (1) an estimate for the Opt-In Payment (the “Opt-In Estimate”), which estimate shall be based upon the development costs already incurred.
by the Conducting Party with respect to such Incremental Study together with those anticipated to be incurred by the Conducting Party, within [*] after the date of such notice (in each case, calculated as described in Section 4.4(c)(v)(A)(1)); and (2) a proposal to amend the Development Plan to convert such Incremental Study to an Additional Study, which amendment shall address the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study. The Conducting Party shall provide such estimate and proposal, together with reasonable documentation of the Conducting Party’s already incurred costs, within [*] after such notice (or such longer period of time as agreed upon in writing by the Parties). The Conducting Party shall promptly answer all reasonable questions posed by, and provide all additional documents reasonably requested by, the Non-Conducting Party with respect to the Opt-In Estimate. The JDC shall discuss such proposed amendment to the Development Plan at its next meeting, whether regularly scheduled or specifically requested under Section 3.2(c). The Conducting Party shall provide, within [*] after such JDC meeting (or such longer period of time as agreed upon in writing by the Parties), any additional information reasonably requested by the Non-Conducting Party’s JDC representatives prior to or during such JDC meeting. The Non-Conducting Party shall be deemed to have exercised its Opt-In Right with respect to such Incremental Study if, within [*] after the JDC meeting at which such proposed amendment to the Development Plan is discussed (or such longer period of time as agreed upon in writing by the Parties), the Conducting Party receives payment of the Opt-In Estimate amount and the JDC submits to the JSC for review and approval an amendment to the Development Plan to convert such Incremental Study to an Additional Study, which amendment addresses the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study. The JSC shall promptly review and approve such amendment to the Development Plan. In the event that Mundipharma is the Conducting Party of any Incremental Study in an Oncology Indication which is the basis upon which Mundipharma receives the [*], and Allos does not exercise its Opt-In Right pursuant to this Section 4.4(c)(v) with respect to such Incremental Study, then Mundipharma shall not be obligated to pay the applicable milestone payment(s) set forth in Section 7.3(a)-(d) with respect to such event for such Indication.

(C) Opt-In for Incremental Study in a Non-Oncology Indication. If the Non-Conducting Party with respect to such Incremental Study in a Non-Oncology Indication is considering exercising its Opt-In Right with respect to such Incremental Study, it shall, no later than [*] after the Opt-In Option Date, notify the Conducting Party in writing and shall request that the Conducting Party provide: (1) an Opt-In Estimate for such Incremental Study; and (2) a proposal to amend the Development Plan to convert such Incremental Study to an Additional Study, which amendment shall address the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study. The Conducting Party shall provide such estimate and proposal, together with reasonable documentation of the Conducting Party’s already incurred costs, within [*] after such notice (or such longer period of time as agreed upon in writing by the Parties). The Conducting Party shall promptly answer all reasonable questions posed by, and provide all additional documents reasonably requested by, the Non-Conducting Party with respect to the Opt-In Estimate. The JDC shall discuss such proposed amendment to the Development Plan at its next meeting, whether regularly scheduled or specifically requested under Section 3.2(c). The Conducting Party shall provide, within [*] after such JDC meeting (or such longer period of time as agreed upon in writing by the Parties), any additional information reasonably requested by the Non-Conducting Party’s JDC representatives prior to or during such JDC meeting. The Non-Conducting Party shall be deemed to have exercised its Opt-In Right with respect to such Incremental Study upon the latter of the Conducting Party’s receipt of payment of the Opt-In Estimate amount and the effective date of an amendment to the Development Plan at its next meeting, whether regularly scheduled or specifically requested under Section 3.2(c). The Conducting Party shall provide, within [*] after such JDC meeting (or such longer period of time as agreed upon in writing by the Parties), any additional information reasonably requested by the Non-Conducting Party’s JDC representatives prior to or during such JDC meeting. If the JDC submits the JSC for review and approval an amendment to the Development Plan to convert such Incremental Study to an Additional Study, which amendment addresses the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study, then prior to the first JSC meeting at which such proposed amendment would be discussed, the Conducting Party’s representatives to the JSC shall submit to the JSC, for its review and approval, a good faith, commercially reasonable (given the facts and circumstances at the time) proposal for milestone payments to be paid upon the events specified in Section 4.4(c)(v)(A)(3). If within [*] after the JDC’s submission of an amendment to the Development Plan to convert such Incremental Study to an Additional Study, which amendment addresses the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study, or such longer period as agreed upon in writing by the Parties, the JSC approves such amendment or a revised version thereof and agrees upon milestone payments to be paid upon the events specified in Section 4.4(c)(v)(A)(3), then the Non-Conducting Party shall be deemed to have exercised its Opt-In Right with respect to such Incremental Study upon the latter of the Conducting Party’s receipt of payment of the Opt-In Estimate amount and the effective date of an amendment to this Agreement that includes such agreed upon milestone payments. If by the end of the [*] period after the JDC’s submission of an amendment to the Development Plan to convert such Incremental Study to an Additional Study, which amendment addresses the items specified in Section 4.4(c)(v)(A)(2), to the extent applicable to such Incremental Study, or such longer period as agreed upon in writing by the Parties, the JSC has not approved such amendment or a revised version thereof and agrees upon milestone payments to be paid upon the events specified in Section 4.4(c)(v)(A)(3), then either Party may submit the dispute for resolution by the Executive Officers of the Parties. If the Parties’ Executive Officers are unable to agree upon such amendment, or a revised version thereof, and milestone payments to be paid, then the Conducting Party shall be entitled to undertake such Incremental Study on its own and the non-Conducting Party shall be deemed to have not exercised its Opt-In Right with respect to such Incremental Study.

(D) Upon exercise of the Opt-In Right with respect to a particular study, such study shall cease to be an Incremental Study and shall be deemed to be an Additional Study, the Parties shall share all future Joint Development Costs associated therewith in accordance with Section 4.5 and the Parties shall have the diligence obligations with respect to such Additional Study as provided in Section 4.2(d). In its first invoice provided
pursuant to Section 7.2 after the actual Opt-In Payment can first be calculated for such former Incremental Study, the former Conducting Party shall include a credit to the former Non-Conducting Party for the amount, if any, by which the Opt-In Estimate exceeded the actual Opt-In Payment or a charge for the amount, if any, by which the actual Opt-In Payment exceeded the Opt-In Estimate.

(d) Related Studies. The agreement by the Parties to any Additional Study under this Section 4.4, whether from the outset of the study pursuant to Sections 4.4(a) or 4.4(b), or through either Party’s exercise of its Opt-In Right to an Incremental Study pursuant to Section 4.4(c)(v), shall be deemed an agreement by the Parties to cooperate in any and all related studies necessary for the implementation of such Additional Study or to obtain Drug Approval in the U.S. and all Major Market Countries in the applicable new Indication or new formulation that is the subject of such Additional Study (excluding any related studies that are required exclusively to obtain Drug Approval in the U.S. and not in any Major Market Country) (each such related study, a “Related Study”). The terms of Section 4.4 shall apply to any Related Study in the same manner that they apply to the Additional Study to which such Related Study relates.

(e) Manufacture. With respect to any Additional Study or Incremental Study (for which either Party is the Conducting Party) that involves a New Form, the Conducting Party shall offer the Non-Conducting Party the opportunity to be the supplier of such New Form. Unless the Non-Conducting Party informs the Conducting Party that it is not interested in being, or is unable to be, the supplier of such New Form, the Parties shall negotiate in good faith and enter into a separate supply agreement that sets forth the terms and conditions under which the Non-Conducting Party will supply such New Form to the Conducting Party (in the event of an Incremental Study) or one or both Parties (in the event of an Additional Study). If the Non-Conducting Party informs the Conducting Party that it is not interested in being, or is unable to be, the supplier of such New Form, then the Non-Conducting Party shall grant to the Conducting Party a non-exclusive, royalty-free limited right and license, under the Allos Manufacturing Know-How and Allos Patents, or Mundipharma Know-How, Mundipharma-Controlled manufacturing-related Information and Mundipharma Patents, as applicable, to manufacture such New Form, with (in the event Mundipharma is the Conducting Party) the right to sublicense in accordance with Section 2.1(f) to its Affiliates or, with the prior written consent of the Non-Conducting Party, to a Third Party manufacturer (which consent shall not be unreasonably withheld, conditioned or delayed), solely for use in accordance with this Agreement.

4.5 Development Costs. The Parties shall each be responsible for their respective share, as defined in this Section 4.5, of all Joint Development Costs. Mundipharma shall be responsible for the “Mundipharma Share” of Joint Development Costs, which share shall initially be forty percent (40%) of the Joint Development Costs and shall become fifty percent (50%) of the Joint Development Costs (the “50/50 Threshold”) (a) in the calendar quarter after Mundipharma receives Conditional Approval or (b) if such Conditional Approval is not obtained, the later of (i) the calendar quarter of the first Drug Approval in the EU of the Product in the Lead Indication or First Line PTCL, and (ii) the first calendar quarter in which the Development Cost Differential equals or exceeds fifteen million Dollars ($15,000,000); provided, if the Development Cost Differential does not equal or exceed fifteen million Dollars ($15,000,000) by December 31, 2019, then Allos shall be required to remit the difference between fifteen million Dollars ($15,000,000) and the Development Cost Differential as of such date to Mundipharma on or before January 31, 2020 and thereafter the Mundipharma Share shall be fifty percent (50%). For purposes of this Section 4.5, the “Development Cost Differential” means the difference between (A) the cumulative amount of Joint Development Costs borne by Mundipharma (whether as reimbursement to Allos pursuant to Section 7.2(a) or as Joint Development Costs directly incurred by Mundipharma to the extent that such Joint Development Costs exceed Allos’ reimbursement to Mundipharma pursuant to Section 7.2(b)), together with any Joint Manufacturing Costs (as defined in the Supply Agreement) borne by MMCO pursuant to the Supply Agreement, and (B) the cumulative amount of Joint Development Costs that Mundipharma would have borne if Mundipharma had been responsible for fifty percent (50%) of Joint Development Costs (rather than forty percent (40%) of Joint Development Costs), together with any Joint Manufacturing Costs (as defined in the Supply Agreement) that MMCO would have borne pursuant to the Supply Agreement if MMCO had been responsible for fifty percent (50%) (rather than forty percent (40%)) of Joint Manufacturing Costs under the Supply Agreement.

4.6 Diligence. Mundipharma and Allos shall each use Reasonably Diligent Efforts to Develop Product in each country in the Licensed Territory in accordance with their respective activities under the Development Plan.
4.7 Investigator-Sponsored Studies.

(a) Before either Party authorizes or facilitates an investigator to conduct an ISS for the Product in the Field that complies with the guidelines established by the JDC pursuant to Section 3.2(a)(iv), such Party shall notify the other Party in writing, which notice shall provide a reasonably detailed description of such ISS and explanation of how it complies with such guidelines.

(b) Before either Party authorizes or facilitates an investigator to conduct an ISS for the Product in the Field that does not comply with the guidelines established by the JDC pursuant to Section 3.2(a)(iv), such Party shall provide the other Party with information relating to such ISS and shall provide the other Party a reasonable opportunity to review and comment upon such ISS. Such Party shall give reasonable consideration to the other Party's comments. The other Party shall have [*] after such information is given (or such longer period of time as agreed upon in writing by the Parties), to allege that the conduct of such ISS is substantially likely to create a Material Impact and if such Party disagrees with such allegation, then the Parties shall bring such disagreement to the JDC for resolution.

(c) ISSs shall not be included in the Development Plan.

(d) A Party authorizing or facilitating an ISS pursuant to this Section 4.7 shall only receive disclosure, access or a license to any Information or Patent arising from such ISS under terms that allow such Party to Control such Information or Patent, such that such Information or Patent shall be included in Allos ISS Technology if such Party is Allos or Mundipharma ISS Technology if such Party is Mundipharma. Such Party shall disclose all such Information and Patents to the other Party promptly following its receipt of disclosure of or access to such Information or Patent.

4.8 Data Exchange and Use. Upon the Effective Date, Allos shall provide Mundipharma with access, free of charge, to all Allos Know-How then in existence that constitutes pre-clinical or clinical data relating to the Product. For clarity, Allos does not have any obligation to disclose or provide access to any Information with respect to manufacture of the Product except in the event the license under Section 2.1(c) becomes effective and then only in accordance with Section 2.1(c) and the Supply Agreement. In addition to its adverse event and safety data reporting obligations pursuant to Section 5.7, each Party shall promptly provide the other Party with access to, at no additional charge:

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(a) all safety, clinical and other development Information (including, if requested, raw data) associated with the conduct of the Shared Studies, as reasonably necessary or useful to support such other Party's Development or Commercialization of the Product in the Field in accordance with this Agreement, including rights of access and reference to Regulatory Materials; and

(b) all safety Information (including, if requested, raw data) generated pursuant to any Incremental Study which the Non-Conducting Party is required by a Regulatory Authority in its territory to file with such Regulatory Authority to support safety disclosure requirements. The Non-Conducting Party shall have no rights to use any other Information arising from such Incremental Study in any filings with Regulatory Authorities in its territory (i.e., in the Allos Territory where Allos is the Non-Conducting Party and in the Licensed Territory where Mundipharma is the Non-Conducting Party) unless and until such Non-Conducting Party exercises its right, pursuant to Section 4.4(c)(v), to convert such Incremental Study to an Additional Study.

4.9 Development Reports. Each Party shall provide the JDC with written reports detailing its Development activities under this Agreement and the results of such activities at least ten (10) days in advance of each regularly scheduled JDC meeting; provided, subject to Section 4.4(c)(iv), such reports will not include the results of any Incremental Studies for which the other Party has not exercised its Opt-In Right and made the payments required to be made under Section 4.4. The Parties shall discuss the status, progress and results of each Party's Development activities under this Agreement at such regularly scheduled JDC meetings.

4.10 Development Records. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all data and other Information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and clinical trials in formal written study records according to applicable Laws, including applicable national and international guidelines such as ICH, GCP and GLP. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times, and upon reasonable notice, to obtain access to the original records to the extent such Party has a license to use the Information contained in such records.

4.11 Compliance with Laws. Each Party shall conduct its activities under this Agreement in a good scientific manner and comply in all material respects with all applicable Laws, including applicable national and international guidelines such as ICH, GCP and GLP.

4.12 Allos’ Other Licensees. For clarity, if Allos grants a Third Party an exclusive license to Develop and/or Commercialize a Product in any country in the Allos Territory, then such licensee may directly exercise Allos' rights pursuant to this Agreement with respect to such Product in such country.

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ARTICLE 5
REGULATORY MATTERS

5.1 Regulatory Responsibilities in the Licensed Territory.

(a) Allos will lead regulatory activities in the EEA with respect to the Product in the Field and use Reasonably Diligent Efforts in respect of the Product in the Lead Indication in the EEA until the date that is the earliest of (i) [*]; (ii) [*]; or (iii) [*] (such date, the "Transfer Date"). Prior to the Transfer Date, Mundipharma will provide non-financial support to Allos with respect to such regulatory activities, up to two (2) representatives (depending upon space constraints) of Mundipharma will be invited to observe all meetings and interactions with Regulatory Authorities in the EEA with respect to the Product in the Field, and Mundipharma will have the right to review draft responses to Regulatory Authority questions with respect to the Product in the Field. Allos will, at its sole expense, transfer to Mundipharma on or around the Transfer Date, ownership of and responsibility for: (1) the DAA filed by Allos and validated by the EMA on December 15, 2010, (2) any and all Regulatory Approvals arising therefrom, (3) all orphan drug authorizations for the Product in the Field in the EEA, and (4) the EU Pediatric Investigation Plan approved by the EMA.

(b) Commencing on the Effective Date with respect to all countries of the Licensed Territory outside the EEA, and commencing on the Transfer Date with respect to countries in the EEA, Mundipharma shall use Reasonably Diligent Efforts in respect of the Product as the primary interface with and shall otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning regulatory activities related to the Product in the Field in the Licensed Territory, and Mundipharma shall be responsible for preparing and filing any and all Regulatory Materials for the Product in the Field in the Licensed Territory at its sole expense in accordance with the Development Plan. Allos shall assist and cooperate at its own expense with Mundipharma in connection with the preparation and filing of such Regulatory Materials, as reasonably requested by Mundipharma, including preparation of ongoing clinical trials, study reports and Periodic Safety Update Reports ("PSURs"). Such cooperation will include promptly responding within procedural timelines set by Regulatory Authorities to any reasonable request from Mundipharma for Allos Know-How needed for the Regulatory Materials. For clarity, Allos shall not be obligated to provide Mundipharma with any Information that is not Allos Know-How.

(c) Subject to Section 5.1(a), Mundipharma shall keep Allos informed at JDC meetings of regulatory developments relating to the Product in the Field in the Licensed Territory and shall promptly notify Allos in writing of any action or decision by any Regulatory Authority in the Licensed Territory regarding the Product in the Field. Mundipharma shall provide Allos for review and comment all draft Regulatory Materials (other than routine correspondence such as IND and MAA annual reports, MAA reapproval, during the investigational phase minor protocol amendments, IND amendments for new investigators or new clinical preclinical studies) at least [*] (or in the event of a shorter filing deadline, as soon as practicable) in advance of their intended date of submission to a Regulatory Authority in the Licensed Territory and shall consider in good faith any comments thereto provided by Allos.

(d) Commencing on the Effective Date with respect to all countries of the Licensed Territory outside the EEA, and commencing on the Transfer Date with respect to countries in the EEA, Mundipharma will provide non-financial support to Allos with respect to such regulatory activities, up to two (2) representatives (depending upon space constraints) of Mundipharma will be invited to observe all meetings and interactions with Regulatory Authorities in the EEA with respect to the Product in the Field, and Mundipharma will have the right to review draft responses to Regulatory Authority questions with respect to the Product in the Field. Allos will, at its sole expense, transfer to Mundipharma on or around the Transfer Date, ownership of and responsibility for: (1) the DAA filed by Allos and validated by the EMA on December 15, 2010, (2) any and all Regulatory Approvals arising therefrom, (3) all orphan drug authorizations for the Product in the Field in the EEA, and (4) the EU Pediatric Investigation Plan approved by the EMA.

(e) Allos shall be responsible for compiling and providing to Mundipharma the CMC Information that is required for Mundipharma to obtain and maintain Regulatory Approval of the Product in the Licensed Territory. Mundipharma shall use the CMC Information provided to it by Allos for the purpose of obtaining and maintaining Regulatory Approval of the Product in the Licensed Territory and in connection with the exercise of its...
license under section 2.1(c). At Mundipharma’s request, Allos shall provide reasonable assistance to Mundipharma with respect to communications with Regulatory Authorities in the Licensed Territory regarding the manufacture of the Product or the CMC Information.

(f) Unless the Parties otherwise agree in writing: (i) except as expressly contemplated by Section 5.1(a), 5.1(b) or 5.1(e), Allos shall not communicate with respect to the Product in the Field with any Regulatory Authority having jurisdiction in the Licensed Territory, or unless so ordered by such Regulatory Authority, in which case Allos shall provide immediate notice to Mundipharma of such order; and (ii) except as expressly contemplated by Section 5.1(a), Allos shall not submit any Regulatory Materials or seek Regulatory Approvals for the Product in the Field in the Licensed Territory.

5.2 Regulatory Responsibilities in the Allos Territory.

(a) Allos shall own all Regulatory Materials (including Regulatory Approvals) for the Product in the Allos Territory, and shall be responsible for preparing and filing any and all Regulatory Materials for the Product in the Allos Territory at its sole expense. Mundipharma shall assist and cooperate with Allos in connection with the preparation and filing of such Regulatory Materials, as reasonably requested by Allos and at Allos’ sole expense.

(b) Allos shall keep Mundipharma informed of regulatory developments relating to the Product in the Field in the Allos Territory through regular reports at the JDC meetings and shall promptly notify Mundipharma in writing of any action or decision by any Regulatory Authority in the Allos Territory relating to the Product. Allos shall provide Mundipharma with review and comment all draft Regulatory Materials (other than routine correspondence such as IND and NDA annual reports, during the investigational phase minor protocol amendments, IND amendments for new investigators or new clinical preclinical studies), at least [ * ] (or in the event of a shorter filing deadline, as soon as practicable) in advance of the intended date of submission to a Regulatory Authority in the Allos Territory and shall consider in good faith any comments thereto provided by Mundipharma. Allos shall promptly notify Mundipharma of any Regulatory Materials (other than routine correspondence such as IND and NDA annual reports, during the investigational phase minor protocol amendments, IND amendments for new investigators or new clinical preclinical studies) submitted to or received from any Regulatory Authorities in the Allos Territory and shall provide Mundipharma with copies thereof, in eCTD format, within [ * ] after submission or receipt.

(c) Unless the Parties otherwise agree in writing: (i) except as expressly contemplated by Section 5.2(a), Mundipharma shall not communicate with respect to the Product with any Regulatory Authority having jurisdiction in the Allos Territory, unless so ordered by such Regulatory Authority, in which case Mundipharma shall provide immediate notice to Allos of such order; and (ii) Mundipharma shall not submit any Regulatory Materials or seek Regulatory Approvals for the Product in the Allos Territory.

5.3 Regulatory Costs. Commencing on [ * ] with respect to [ * ], and commencing on [ * ] with respect to [ * ] shall be solely responsible for all of its costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for [ * ] shall be solely responsible for all costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for [ * ].

5.4 Rights of Reference to Regulatory Materials. Allos hereby grants to Mundipharma a right of reference to all Regulatory Materials filed by or on behalf of Allos, which right of reference Mundipharma may use for the sole purpose of seeking, obtaining and maintaining Regulatory Approvals and Developing and Commercializing the Product in the Field in the Licensed Territory. Mundipharma hereby grants to Allos and Allos’ licensees in the Allos Territory a right of reference to all Regulatory Materials filed by or on behalf of Mundipharma, which right of reference Allos may use for the sole purpose of seeking, obtaining and maintaining Regulatory Approvals and Developing and Commercializing the Product in the Field in the Allos Territory. Each Party shall support the other Party, as reasonably requested by such other Party, in obtaining Regulatory Approvals in such other Party’s territory, including providing necessary documents or other materials required by applicable Laws to obtain Regulatory Approval in such territory, all in accordance with the terms and conditions of this Agreement.

5.5 No Harmful Actions.

(a) If Allos reasonably believes that Mundipharma is taking or intends to take any action with respect to the Product that is substantially likely to have a Material Impact in the Allos Territory, Allos shall have the right to bring the matter to the attention of the JSC.
Mundipharma shall not proceed with any such action or alternative course of action until it is approved by the JSC in accordance with Section 3.1(d).

(b) If Mundipharma reasonably believes that Allos is taking or intends to take any action with respect to the Product that is substantially likely to have a Material Impact in the Licensed Territory, Mundipharma shall have the right to bring the matter to the attention of the JSC. Allos shall not proceed with any such action or alternative course of action until it is approved by the JSC in accordance with Section 3.1(d).  

5.6 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may affect the Development, Commercialization or regulatory status of the Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

5.7 Adverse Event Reporting and Safety Data Exchange.

(a) Within [*] after the Effective Date, the Parties shall define and finalize the actions that the Parties shall employ with respect to Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning Product safety. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory or safety reporting requirements, in which case local reporting requirements shall prevail. Mundipharma shall be responsible for reporting quality complaints, adverse events and safety data related to Products in the Field to applicable Regulatory Authorities in the Licensed Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Products in the Field in the Licensed Territory. The Pharmacovigilance Agreement shall also provide for a worldwide safety database to be maintained by Allos. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and sublicensees to comply with such obligations.

(b) Prior to the execution of such Pharmacovigilance Agreement, the terms of this Section 5.7(b) shall apply. The Parties agree to coordinate their pharmacovigilance procedures in connection with the Development of Products, and Allos shall submit to Mundipharma all safety information and reporting in a manner that meets reporting requirements under applicable Laws in the Licensed Territory. Allos shall notify Mundipharma within twenty-four (24) hours of receipt of any Serious Adverse Event. Allos shall also provide Mundipharma, on a quarterly basis, with a summary report of Adverse Events, PSURs, investigator brochures and updates to same. As used herein, unless defined differently by the FDA or EMA, (i) "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product, such that an Adverse Event can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product, and (ii) "Serious Adverse Event" means an Adverse Event which results in death, is immediately life-threatening, results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or requires in-patient hospitalization or prolongation of existing hospitalization, results in a congenital anomaly/birth defect, or is an important medical event that may jeopardize the patient or may require intervention to prevent one of the outcomes listed in this definition. Mundipharma shall not participate in any Development activities or engage any subcontractor to perform any Development activities on its behalf prior to the execution of the Pharmacovigilance Agreement.

5.8 Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Product may be subject to any recall, corrective or other regulatory action taken by virtue of applicable Laws (a "Remedial Action"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Each Party shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to permit the Parties to trace the manufacture, distribution and use of the Product. In the event Mundipharma determines that any Remedial Action with respect to the Product in the Field in the Licensed Territory should be commenced or is required by the applicable Regulatory Authority, Mundipharma shall have the right to control and coordinate all efforts necessary to conduct such Remedial Action; provided that, with respect to any such Remedial Action that is not imposed upon Mundipharma by applicable Law or a Regulatory Authority, such Remedial Action shall have been reviewed and approved by the JSC. If the JSC fails to approve
ARTICLE 6

COMMERCIALIZATION

6.1 Overview of Commercialization in the Licensed Territory. Subject to the terms and conditions of this Article 6, as between the Parties, Mundipharma will be responsible for all aspects of the Commercialization of the Product in the Field in the Licensed Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of the Product; (c) marketing and promotion; (d) booking sales, and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of the Product in the Field in the Licensed Territory. Mundipharma shall bear all of the costs and expenses incurred in connection with such Commercialization activities.

6.2 Commercialization Plan for Licensed Territory.

(a) General. Mundipharma shall Commercialize the Product in the Field in the Licensed Territory pursuant to a detailed plan prepared by Mundipharma and submitted by Mundipharma to the JCC for review and comment and by the JCC to the JSC for review and discussion (the "Commercialization Plan"). The Commercialization Plan will include (i) a reasonably detailed description and timeline of Mundipharma’s Commercialization activities in the Field in each of the Major Market Countries for the next year, including medical marketing activities, sales forecasts and projections, pricing, reimbursement, market research, sales training, distribution channels, customer service and sales force matters related to the launch and sale of the Product in each country in such year, (ii) an overview of Mundipharma’s Commercialization activities in the Field in all other countries in the Licensed Territory for the next year and (iii) a strategic plan for Commercialization of the Product in the Field in the Licensed Territory for the following two (2) years.

(b) Initial Plan and Amendments. The initial Commercialization Plan shall be delivered to the JCC no later than [*] after the Effective Date or [*] before the anticipated launch of the Product in the Licensed Territory, whichever is later, for review and comment, after which the JCC shall submit such initial Commercialization Plan to the JSC for review and discussion. On at least an annual basis, Mundipharma shall prepare an amendment, as appropriate, to the then-current Commercialization Plan. Mundipharma shall submit all amendments to the Commercialization Plan to the JCC for review and comment, after which the JCC shall submit such amendment to the JSC for review and discussion. Once reviewed by the JSC, the amended Commercialization Plan shall become effective and supersede the previous Commercialization Plan as of the date of such review.

6.3 Pricing. Mundipharma shall have the sole right to determine all pricing of Products in the Field in the Licensed Territory. For the avoidance of doubt, Allos shall not have any right to direct, control, or approve Mundipharma’s pricing of Products in the Field in the Licensed Territory.

6.4 Pricing Approval. On a country-by-country basis and subject to Section 6.6(b), Mundipharma will use Reasonably Diligent Efforts to obtain and maintain Pricing Approval for the Product in the Field in each country in the Licensed Territory in which it has obtained Drug Approval for such Product in the Field. Without limiting the foregoing, and subject to the Product’s launch sequence as reviewed and discussed by the JCC, Mundipharma shall file for Pricing Approval in each EU Major Market Country [*].

6.5 Reimbursement Approval. On a country-by-country basis and subject to Section 6.6(b), Mundipharma will use Reasonably Diligent Efforts to obtain and maintain Reimbursement Approval for the Product in the Field in each country in the Licensed Territory in which it has obtained Drug Approval for such Product in the Field.
6.6 Commercial Diligence.

(a) Mundipharma shall use Reasonably Diligent Efforts to Commercialize the Product in the Field in each country in the Licensed Territory in which it receives Regulatory Approval. After the launch of a Product, Mundipharma shall [*].

(b) Mundipharma shall achieve First Reimbursable Commercial Sale of each Product in a country within [*] after all Regulatory Approvals have been obtained to Commercialize the Product in the Field in such country; provided, however, that Mundipharma is not obligated to launch a particular Product in a particular country in the Licensed Territory if [*] and provides Allos, within [*] of receipt of final Regulatory Approval in such country, with written notice [*]. Allos may, within a reasonable time after receiving such written notice from Mundipharma, submit any dispute to the JSC for review and approval and, in the absence of such approval, the terms of Section 13.2 shall apply. Notwithstanding the foregoing or the terms of Section 13.1 or 13.2, if Allos disputes [*] and if neither the JSC nor the Parties’ Executive Officers are able to resolve such dispute, such dispute shall be resolved by a mutually acceptable, disinterested, conflict-of-interest-free individual (the “Expert”) as follows:

(i) Upon the written request of either Party, the Parties shall promptly negotiate in good faith to appoint an appropriate Expert who shall have such scientific, technical, regulatory and commercial experience as is necessary to resolve such dispute and who shall not be or have been during the preceding five (5) years an Affiliate, employee, consultant, officer or director of either Party or any of their respective Affiliates. If the Parties are not able to agree upon an Expert within [*] after the receipt by a Party of the written request in the immediately preceding sentence, each Party shall select one (1) Expert within [*] thereafter, and those two (2) Experts shall select a third Expert within [*] thereafter and such third Expert (selected by the first two Experts) shall be the designated Expert for resolution of the dispute. The fees and costs of the Expert shall be borne equally (50-50) by Allos and Mundipharma.

(ii) Within [*] after the designation of the Expert, the Parties shall each submit to the Expert and to one another a written statement of their respective positions on whether [*]. Each Party shall have [*] from receipt of the other Party’s submission to submit a written response thereto, which shall include any scientific, commercial and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

(iii) No later than [*] after the designation of the Expert, the Expert shall make a determination by selecting the position of one of the Parties that as a whole is the most fair and reasonable to the Parties in light of the totality of the circumstances and the Expert shall provide the Parties with a written statement setting forth the basis of the determination in connection therewith. The Expert shall not have authority to render any substantive decision other than to select the position proposed by Allos or Mundipharma. The determination of the Expert shall be final and conclusive. If the Expert determines that [*], Mundipharma shall promptly thereafter launch the Product and shall use Reasonably Diligent Efforts to Commercialize the Product in the Field in such country. Failure by Mundipharma to launch the Product in such country in the Licensed Territory after the Expert determines that [*] shall (A) with respect to any Major Market Country, [*], and (B) with respect to any country in the Licensed Territory other than a Major Market Country, [*]: provided that [*].

6.7 Cross-Territorial Restrictions.

(a) Mundipharma hereby covenants and agrees that, insofar as permitted by applicable Law, it shall not, and shall ensure that its Affiliates and Sublicensees will not, either directly or indirectly, knowingly promote, market, distribute, import, sell or have sold any Product, including via internet or mail order, into countries in the Allos Territory. As to such countries in the Allos Territory, Mundipharma shall not achieve First Reimbursable Commercial Sale of each Product in a country within [*] after all Regulatory Approvals have been obtained to Commercialize the Product in the Field in such country; provided, however, that Mundipharma is not obligated to launch a particular Product in a particular country in the Allos Territory if [*] and provides Allos, within [*] of receipt of final Regulatory Approval in such country, with written notice [*]. Mundipharma shall not deliver or tender (or cause to be delivered or tendered) any Product into a country in the Allos Territory. Mundipharma shall not, and shall ensure that its Affiliates and Sublicensees will not, restrict or impede in any manner Allos’ exercise of its retained rights in the Allos Territory.

(b) Allos hereby covenants and agrees that, except with respect to the named patient supply program in effect as of the Effective Date or any named patient supply program implemented after the Effective Date and approved by Mundipharma, insofar as permitted by applicable Law, it shall not, and shall ensure that its Affiliates and sublicensees will not, either directly or indirectly, knowingly promote, market, distribute, import, sell or have sold any Product, including via internet or mail order, into countries in the Allos Territory. As to such countries in the Allos Territory, Allos shall not, and shall ensure that its Affiliates and sublicensees will not: (i) except with respect to any such named patient supply program, establish or maintain any branch, warehouse or distribution facility for any Product in such country; or (ii) engage in any advertising or promotional activities relating to any Product that are directed primarily to customers or other purchasers or users of such Product located in such countries; or (iii) sell or distribute any Product to any person in the Allos Territory who it knows intends to sell any Product in such countries. If Mundipharma receives any order from a prospective purchaser located in a country in the Allos Territory, Mundipharma shall immediately refer that order to Allos.

[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

written response thereto, which shall include any scientific, commercial and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

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countries, (ii) engage in any advertising or promotional activities relating to any Product that are directed primarily to customers or other purchasers or users of such Product located in such countries (but, for the avoidance of doubt, the foregoing shall not in any way restrict Allos from responding to medical information requests in connection with any such named patient supply program), (iii) solicit orders from any prospective purchaser located in such countries, or (iv) except with respect to any such named patient supply program, sell or distribute any Product to any person in the Allos Territory who it knows intends to sell any Product in such countries. If Allos receives any order from a prospective purchaser located in a country in the Licensed Territory except for orders in connection with any such named patient supply program, Allos shall immediately refer that order to Mundipharma, and Allos shall not accept any such orders. Allos shall not deliver or tender (or cause to be delivered or tendered) any Product into a country in the Licensed Territory except in connection with any such named patient supply program. Allos shall not, and shall ensure that its Affiliates and sublicensees will not, restrict or impede in any manner (other than with respect to any such named patient supply program) Mundipharma’s exercise of its licensed rights in the Licensed Territory. For clarity, nothing in this Section 6.7(b) shall preclude or prohibit Allos, directly or indirectly, itself or through its Affiliates or any Third Party, from distributing, importing, selling or having sold any Product in the Licensed Territory as part of or in connection with a named patient supply program in effect as of the Effective Date or a named patient supply program implemented after the Effective Date and approved by Mundipharma; provided that, on a country-by-country basis in the Licensed Territory, Allos shall discontinue any such named patient supply program in a country in the Licensed Territory, in accordance with the terms of such named patient supply program agreement, upon obtaining the first Drug Approval in such country unless continuation of such named patient supply program in such country is approved by Mundipharma. In the event that Mundipharma approves continuation of such named patient supply program in a country in the Licensed Territory following Drug Approval in such country, and if Mundipharma later provides written notice to Allos requesting discontinuation of such named patient supply program in such country, Allos shall thereafter discontinue such named patient supply program in such country in accordance with the terms of such named patient supply program agreement. Notwithstanding the foregoing, Mundipharma may elect, at any time during the Term, to take over the existing named patient supply program, on such terms as may be mutually agreed by the Parties and the existing named patient supply program distributor.

6.8 Territorial Coordination. The Parties shall, where appropriate, coordinate their Commercialization activities between the Allos Territory and the Licensed Territory, through the JCC, which coordination may include implementation of a global branding strategy for the Product.

6.9 Reports. Each Party shall update the JCC at each regularly scheduled JCC meeting regarding its Commercialization activities with respect to Products in the Field in its applicable territory. Each such update shall be in a form to be agreed by the JCC and shall summarize such Party’s significant Commercialization activities with respect to Products in the Field in its applicable territory pursuant to this Agreement, covering subject matter at a level of detail reasonably requested by the Parties and sufficient to enable each Party to assess the other Party’s compliance with its obligations pursuant to Section 6.6.

7.1 Upfront Payment. In partial consideration of Allos’ investment in Development of the Product in the Field prior to the Effective Date, Allos’ provision to Mundipharma of access to regulatory filings and clinical data generated by Allos with respect to the Product in the Field, and Allos’ grant of an exclusive license to Mundipharma under the Allos Technology, Mundipharma shall pay to Allos a one-time upfront fee of fifty million Dollars ($50,000,000) within ten (10) days after the Effective Date. Such fee shall be non-creditable and non-refundable.

7.2 Reimbursement of Joint Development Costs.

(a) Mundipharma shall be responsible for the Mundipharma Share of all Joint Development Costs. Within [*] after the end of each calendar quarter during which Allos has incurred any Joint Development Costs, Allos shall submit to Mundipharma a reasonably detailed invoice setting forth the total Joint Development Costs incurred by Allos in such calendar quarter and invoicing Mundipharma for the Mundipharma Share of such Joint Development Costs. Mundipharma shall pay to Allos the amount invoiced within [*] after the receipt of such invoice. Allos will also provide to Mundipharma a monthly statement of account reflecting the Mundipharma Share of Joint Development Costs previously due and owing that remains outstanding, if any.

(b) Allos shall be responsible for the Allos Share of all Joint Development Costs. Within [*] after the end of each calendar quarter during which Mundipharma has incurred any Joint Development Costs, Mundipharma shall submit to Allos a reasonably detailed invoice setting forth the total
Joint Development Costs incurred by Mundipharma in such calendar quarter and invoicing Allos for the Allos Share of such Joint Development Costs. Allos shall pay to Mundipharma the amount invoiced within [*] after the receipt of such invoice. Mundipharma will also provide to Allos a monthly statement of account reflecting the Allos Share of Joint Development Costs previously due and owing that remains outstanding, if any.

(c) All payments made by a Party pursuant to this Section 7.2 shall be non-refundable.

(d) Unless Mundipharma elects to exercise its right to terminate this Agreement pursuant to Section 12.2 for Allos’ failure to pay the Allos Share of Joint Development Costs within [*] after delivery by Mundipharma of an invoice to Allos for the Allos Share of Joint Development Costs pursuant to Section 7.2(b) (provided that Allos does not, within [*] after Allos receives such invoice, have a bona fide, good faith dispute in respect thereof), any Allos Unpaid Reimbursement Amount shall be deducted from Mundipharma’s payments as provided in Sections 7.3 and 7.4 and, following such deduction, the amount of the Allos Share of Joint Development Costs that was included in the deducted Allos Unpaid Reimbursement Amount shall be deemed paid in full and no longer due and payable (and, for clarity, such amount shall not be included in any future Allos Unpaid Reimbursement Amount to Mundipharma). Unless Allos elects to exercise its right to terminate this Agreement pursuant to Section 12.2 for Mundipharma’s failure to pay the Mundipharma Share of Joint Development Costs within [*] after delivery by Allos of an invoice to Mundipharma for the Mundipharma Share of Joint Development Costs pursuant to Section 7.2(a) (provided that Mundipharma does not, within [*] after Mundipharma receives such invoice, have a bona fide, good faith dispute in respect thereof), Allos shall be entitled to deduct from any future payments owed by Allos to Mundipharma under this Agreement [*] of the sum of the unpaid Mundipharma Share of Joint Development Costs and interest on such unpaid Mundipharma Share of Joint Development Costs from the date originally due as provided in Section 7.7 and, following such deduction, the amount of the Mundipharma Share of Joint Development Costs that was deducted shall be deemed paid in full and no longer due and payable.

(e) Notwithstanding the foregoing or the terms of Sections 7.3 and 7.4, if, following completion of a Change of Control of Allos, Mundipharma elects not to terminate this Agreement and does not deliver written notice of termination under Section 12.4(a) within [*] of delivery of the Allos Change of Control Notice, then any Allos Unpaid Reimbursement Amount that is outstanding as of the date that is [*] after delivery of the Allos Change of Control Notice shall be paid in full by Allos (or its Acquiror) [*] thereafter.

7.3 Milestone Payments.

(a) Drug Approval.

(i) Within [*] after the receipt of the first Drug Approval of the Product for the Lead Indication in the EU, Mundipharma shall pay to Allos a one-time, non-refundable, non-creditable milestone payment of either (i) fourteen million five hundred thousand Dollars ($14,500,000) if such Drug Approval is a Conditional Approval or (ii) [*] if such Drug Approval is not a Conditional Approval, minus the Allos Unpaid Reimbursement Amount, if any.

(ii) Within [*] after the receipt of the first Drug Approval of the Product for First Line PTCL in the EU, Mundipharma shall pay to Allos a one-time, non-refundable, non-creditable milestone payment of [*], minus the Allos Unpaid Reimbursement Amount, if any.

(b) First Reimbursable Commercial Sale in the EU. Within [*] after each First Reimbursable Commercial Sale of the Product in the Field in the EU as set forth below, Mundipharma shall pay to Allos the applicable one-time, non-refundable, non-creditable milestone payment set forth below, minus the Allos Unpaid Reimbursement Amount, if any:

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Reimbursable Commercial Sale in the Lead Indication in the third (3rd) EU Major Market Country in which such First Reimbursable Commercial Sale occurs</td>
<td>$10,000,000</td>
</tr>
</tbody>
</table>

[ * ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
(c) Drug Approval [*]. Within [*] after [*], Mundipharma shall pay to Allos a one-time, non-refundable, non-creditable milestone payment of [*], minus the Allos Unpaid Reimbursement Amount, if any.

(d) First Reimbursable Commercial Sale [*]. Within [*] as set forth below, Mundipharma shall pay to Allos the applicable one-time, non-refundable, non-creditable milestone payment set forth below, minus the Allos Unpaid Reimbursement Amount, if any:

Milestone Event

Milestone Payment

[*]

[*]

[*]

[*]

[*]

[*]

[*]

[*] if [*] or [*]

[*]

[*] if [*] and [*]; or [*] if [*] and [*]; or [*] if [*]

[*]

[*] only if [*] and [*]
(e) Net Sales Milestone Payments in the Licensed Territory. Mundipharma shall make the following one-time, non-refundable, non-creditable milestone payments to Allos when the aggregate Net Sales of all Products in the Licensed Territory (adjusted for any rebates that are known to be required in respect of the calendar year in question) first reach the specified amount listed in the “Milestone Event” column below in any calendar year. Mundipharma shall pay to Allos such amount within [*] after the end of the calendar quarter in which such Milestone Event is achieved, minus the Allos Unpaid Reimbursement Amount, if any. For clarity, the milestone payments in this Section 7.3(e) shall each be paid only once and shall be additive such that if all five Milestone Events set forth below are achieved in the same calendar year, Mundipharma shall pay to Allos a payment of [*].

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>First achievement of aggregate annual Net Sales of all Products in the Licensed Territory equal to or exceeding [*]</td>
<td>$[*]</td>
</tr>
<tr>
<td>First achievement of aggregate annual Net Sales of all Products in the Licensed Territory equal to or exceeding [*]</td>
<td>$[*]</td>
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<td>First achievement of aggregate annual Net Sales of all Products in the Licensed Territory equal to or exceeding [*]</td>
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<td>First achievement of aggregate annual Net Sales of all Products in the Licensed Territory equal to or exceeding [*]</td>
<td>$[*]</td>
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<tr>
<td>First achievement of aggregate annual Net Sales of all Products in the Licensed Territory equal to or exceeding [*]</td>
<td>$[*]</td>
</tr>
</tbody>
</table>

7.4 Royalties.

(a) Royalty Rates. Mundipharma shall pay to Allos non-refundable, non-creditable royalties on Net Sales of all Products in the Licensed Territory during the Royalty Term, as calculated by multiplying the applicable royalty rate set forth below (subject to Sections 7.4(c), 7.4(d) and 7.4(e)) by the corresponding amount of incremental, aggregated Net Sales of all Products in the Licensed Territory in such calendar year [*].
shall apply on a calendar quarter-by-calendar quarter basis and the royalty reductions.

(b) Royalty Term. Royalties shall be paid under this Section 7.4 on a country-by-country basis in the Licensed Territory for Net Sales of Product made during the period from the First Commercial Sale of such Product in such country until the later of: (i) the unappealable revocation of the last, or expiration of the last to expire, PDX Patent in any country in the world; (ii) the expiration or revocation of the last Allos Patent (excluding the PDX Patents), Joint Patent (if such Joint Patent claims the Product or the API or the manufacture or use in the Field of the Product or the API) or Mundipharma Patent in such country; and (iii) the [*] anniversary of the First Commercial Sale of such Product in such country (such period, the “Royalty Term”).

(c) Royalty Reductions for Generic Products. The royalty rates then applicable (i.e., as set forth in Section 7.4(a) and as such royalties may have been further reduced pursuant to Sections 7.4(d) and 7.4(e)) for Product sold in a particular country in the Licensed Territory during a particular calendar quarter shall be reduced, on a calendar quarter-by-calendar quarter and country-by-country basis, in accordance with the following if, following the launch of a Generic Product in such country (or, with respect to the EEA, following the launch of a Generic Product in any one or more country(ies) in the EEA), the sum of the Percentage Price Reduction in such country plus the Percentage Market Penetration in such country reaches the following percentage thresholds: (i) during any calendar quarter in which the sum of the Percentage Price Reduction and the Percentage Market Penetration in a country in the Licensed Territory is equal to or greater than [*] but less than [*], the royalty rates for such calendar quarter for Product sold in such country shall be reduced to [*] of the royalty rates then applicable; (ii) during any calendar quarter in which the sum of the Percentage Price Reduction and the Percentage Market Penetration in a country in the Licensed Territory is equal to or greater than [*] but less than [*], the royalty rates for such calendar quarter for Product sold in such country shall be reduced to [*] of the royalty rates then applicable; (iii) during any calendar quarter in which the sum of the Percentage Price Reduction and the Percentage Market Penetration in a country in the Licensed Territory is equal to or greater than [*] but less than [*], the royalty rates for such calendar quarter for Product sold in such country shall be reduced to [*] of the royalty rates then applicable; (iv) during any calendar quarter in which the sum of the Percentage Price Reduction and the Percentage Market Penetration in a country in the Licensed Territory is equal to or greater than [*], the royalty rates for such calendar quarter for Product sold in such country shall be reduced to [*]. For clarity, the foregoing percentage thresholds shall apply on a calendar quarter-by-calendar quarter basis and the royalty reductions.

(d) Royalty Reduction Upon Reduction or Cessation of PDX License Royalties. In the event royalties cease to be payable by Allos under the PDX License Agreement, the royalty rates in Section 7.4(a) of this Agreement shall be reduced to [*] for that portion of annual aggregated Net Sales of all Products in the Licensed Territory less than or equal to [*]; [*] for that portion of annual aggregated Net Sales of all Products in the Licensed Territory greater than [*] but less than or equal to [*]; and [*] for that portion of annual aggregated Net Sales of all Products in the Licensed Territory greater than [*]; provided, such royalty rates may be further reduced pursuant to Sections 7.4(c) and 7.4(e).

(e) Royalty Reduction For Third Party License. If, during the Term, Mundipharma deems it necessary to seek or obtain a license from any Third Party in order to Develop and Commercialize a Product in the Licensed Territory and provided that Allos is named as or otherwise obtains rights as a licensee or sublicensee (in respect of the Licensed Territory) under such Third Party License, Mundipharma shall be entitled to offset against royalties otherwise due to Allos under this Agreement an amount equal to [*] of any royalties or other fees paid by Mundipharma to such Third Party under such license; provided, however, in no event shall the reduction provided for in this Section 7.4(e) reduce the royalties payable to Allos during any calendar year by more than [*]; provided, such royalty rates may be further reduced pursuant to Sections 7.4(c) and 7.4(d).

(f) Royalty Reports and Payments. Within [*] following the end of each calendar quarter, commencing with the calendar quarter in which the First Commercial Sale of the Product is made anywhere in the Licensed Territory, Mundipharma shall provide Allos with a report containing the following information for such calendar quarter, on a country-by-country basis: (i) the amount of gross sales of Product in the Licensed Territory,
(ii) an itemized calculation of Net Sales in the Licensed Territory showing deductions provided for in the definition of “Net Sales” and any rebates that are known to be required in respect of the calendar year in question, (iii) the conversion of such Net Sales from the currency of sale into Dollars, and (iv) the calculation of the royalty payment due on such sales, showing the application of the reduction, if any, made in accordance with the terms of Sections 7.4(c), 7.4(d) and 7.4(e). Concurrent with the delivery of the applicable quarterly report, Mundipharma shall pay in Dollars all amounts due to Allos pursuant to this Section 7.4 with respect to Net Sales by Mundipharma, its Affiliates and their respective Sublicensees for such calendar quarter.

7.5 Blocked Currency. In each country in the Licensed Territory where the local currency is blocked and cannot be removed from the country, royalties accrued on Net Sales in such country shall be paid to Allos in the equivalent amount in Dollars.

7.6 Foreign Exchange. Conversion of sales recorded in local currencies to Dollars shall be calculated, on a quarterly basis, using the mid-point rate of exchange for the last business day of the calendar quarter as reported in the Financial Times (London edition) on the last business day of each calendar quarter in the quarter prior to the date of payment.

7.7 Payment Method; Late Payments. All payments due hereunder shall be made in Dollars by wire transfer of immediately available funds into an account designated by the Party that is owed such payment (such Party, the “Payee”). If the Payee does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to the Payee until the date of payment at the per annum rate of [ * ] over the then-current prime rate as reported in The Wall Street Journal or the maximum rate allowable by applicable Laws, whichever is lower.

7.8 Records. Each Party shall keep (and shall ensure that its Affiliates and sublicensees keep) such records as are required to determine, in accordance with U.S. generally accepted accounting principles or international financial reporting standards, as applicable, and this Agreement, the sums or credits due under this Agreement, including Joint Development Costs and Net Sales. All such books, records and accounts shall be retained by such Party until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by applicable Laws. Each Party shall require its sublicensees to provide to it a report detailing the foregoing expenses and calculations incurred or made by such sublicensee, which report shall be made available to the other Party in connection with any audit conducted by such other Party pursuant to Section 7.9.

7.9 Audits. Each Party shall have the right to have an independent certified public accountant, reasonably acceptable to the audited Party, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the audited Party (and its Affiliates and sublicensees) as may be reasonably necessary to determine, with respect to any calendar year ending not more than three (3) years prior to such Party’s request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Reports of the results of any such examination shall be (a) limited to details of any discrepancies in the audited Party’s records relating to the Product, (b) made available to both Parties and (c) subject to Article 11. If the audit report concludes that (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 7.7 or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, with interest from the date when the original payment was made, in either case ((i) or (ii)), within [ * ] after the date on which such audit report is delivered to both Parties. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit, which covers the entire calendar year, discloses a variance to the detriment of the auditing Party of more than [ * ] from the amount of the original report, royalty or payment calculation, in which case the auditing Party shall bear the full cost of the performance of such audit. The results of such audit shall be final, absent manifest error.

7.10 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by one Party to the other Party under this Agreement. To the extent a Party is required to deduct and withhold taxes on any payment to the other Party, it shall pay the amounts of such taxes to the
(c) Mundipharma Payments.

(i) Taxes Resulting From Mundipharma Action. If Mundipharma is required to make a payment to Allos that is subject to a deduction or withholding of tax, then (A) if such withholding or deduction obligation arises as a result of any action by Mundipharma, including any assignment or sublicense, any performance by a Mundipharma Affiliate (pursuant to Section 14.6), or any failure on the part of Mundipharma to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a “Mundipharma Payment-Mundipharma Withholding Tax Action”), then the sum payable by Mundipharma (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Mundipharma receives a sum equal to the sum which it would have received had such Mundipharma Payment-Mundipharma Withholding Tax Action occurred, and (B) otherwise, the sum payable by Mundipharma (in respect of which such deduction or withholding is required to be made) shall be made to Allos after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the proper Governmental Authority in accordance with applicable Laws. If Mundipharma subsequently receives a refund of any of the tax deducted by Allos pursuant to (A) above, it shall pay such refunded amount to Mundipharma within [*] of receipt.

(ii) Taxes Resulting From Allos Action. If Allos is required to make a payment to Mundipharma that is subject to a deduction or withholding of tax, then (A) if such withholding or deduction obligation arises as a result of any action by Allos, including any assignment or sublicense, any performance by an Allos Affiliate (pursuant to Section 14.6), or any failure on the part of Allos to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a “Mundipharma Payment-Allos Withholding Tax Action”), then Mundipharma shall be under no obligation to increase the sum payable by Mundipharma (in respect of which such deduction or withholding is required to be made) and the sum payable by Mundipharma shall be net of any withholding obligations resulting from such Mundipharma Payment-Allos Withholding Tax Action.

(d) Allos Payments.

(i) Taxes Resulting From Allos Action. If Allos is required to make a payment to Mundipharma that is subject to a deduction or withholding of tax, then (A) if such withholding or deduction obligation arises as a result of any action by Allos, including any assignment or sublicense, any performance by an Allos Affiliate (pursuant to Section 14.6), or any failure on the part of Allos to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a “Mundipharma Payment-Allos Withholding Tax Action”), then the sum payable by Allos (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Mundipharma receives a sum equal to the sum which it would have received had such Allos Payment-Allos Withholding Tax Action occurred, and (B) otherwise, the sum payable by Allos (in respect of which such deduction or withholding is required to be made) shall be made to Mundipharma after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the proper Governmental Authority in accordance with applicable Laws. If Allos subsequently receives a refund of any of the tax deducted by Mundipharma pursuant to (A) above, it shall pay such refunded amount to Mundipharma within [*] of receipt.

(ii) Taxes Resulting From Mundipharma Action. If Mundipharma is required to make a payment to Allos that is subject to a deduction or withholding of tax, then if such withholding or deduction obligation arises as a result of any action by Mundipharma, including any assignment or sublicense, any performance by a Mundipharma Affiliate (pursuant to Section 14.6), or any failure on the part of Mundipharma to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (an “Allos Payment-Mundipharma Withholding Tax Action”), then Allos shall be under no obligation to increase the sum payable by Allos (in respect of which such deduction or withholding is required to be made) and the sum payable by Allos shall be net of any withholding obligations resulting from such Allos Payment-Mundipharma Withholding Tax Action.

ARTICLE 8

INTELLECTUAL PROPERTY MATTERS

8.1 Ownership of Inventions. Each Party shall own any inventions, whether or not patentable, made solely by its own employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights
Section 8.3 Prosecution of Patents.

(a) Subject to Section 8.3(b), as between the Parties, Allos shall have the sole right to prepare, file, prosecute and maintain Allos Patents, Joint Patents and Mundipharma Patents (collectively, the “Allos Prosecuted Patents”). As between the Parties, [*] shall bear all costs incurred by Allos in connection with the preparation, filing, prosecution or maintenance of any Allos Prosecuted Patent in the Allos Territory. Prior to any filing or extension, Allos shall provide Mundipharma reasonable opportunity to review and comment on such prosecution efforts regarding the Allos Prosecuted Patents (including the PDX Patents, to the extent the PDX Licensor consults with Allos and provides Allos the right to review and comment on the same, in each case as is required pursuant to section 8.2 of the PDX License Agreement) as follows: Allos shall promptly provide Mundipharma with copies of all material communications from any patent authority regarding the Allos Prosecuted Patents. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provided in this Section 8.3(a), including executing any other required documents or instruments for such prosecution.

(b) Except with respect to the PDX Patents, if Allos decides anywhere in the Licensed Territory to abandon any Allos Prosecuted Patent or not to apply for an extension of any Allos Prosecuted Patent, including a supplementary protection certificate or equivalent thereof, Mundipharma shall have the right to assume Allos’ rights and responsibilities under this Section 8.3 with respect to such Allos Prosecuted Patent, and in connection with assuming such rights and responsibilities, Mundipharma shall be entitled to apply for any such extension (including a supplementary protection certificate or equivalent thereof) and Mundipharma shall thereafter become responsible for the prosecution and maintenance of such Allos Prosecuted Patent in the Licensed Territory. With respect to any PDX Patent, the foregoing shall apply only if and to the extent that Allos assumes responsibility and control (after consultation with Mundipharma as to whether to assume such responsibility or control) of the prosecution and maintenance of such PDX Patent in accordance with the PDX License Agreement.

8.4 Patent Enforcement in the Licensed Territory.

(a) Notification. If either Party become aware of any existing or threatened infringement of the Allos Patents, Joint Patents or Mundipharma Patents in the Field in theLicensed Territory by a Third Party (“Licensed Territory Infringement”), it shall promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Licensed Territory Infringement.

(b) Enforcement Rights. For any Licensed Territory Infringement, each Party shall share with the other Party all Information available to it regarding such actual or alleged infringement. As between the Parties, Mundipharma shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Licensed Territory Infringement, at Mundipharma’s cost and expense. Mundipharma shall have a period of ninety (90) days after its receipt or delivery of notice under Section 8.4(a) to elect to so enforce the Joint Patents, Allos Patents or Mundipharma Patents against such Licensed Territory Infringement (or to settle or otherwise secure the
abatement of such Licensed Territory Infringement), if Mundipharma fails to commence a suit to enforce the applicable Joint Patents, Allos Patents or Mundipharma Patents against such Licensed Territory Infringement or to settle or otherwise secure the abatement of such Licensed Territory Infringement within such period, then Allos shall have the right, but not the obligation, to commence a suit or take action to enforce such Joint Patents, Allos Patents or Mundipharma Patents against such Licensed Territory Infringement at its own cost and expense. In this case, Mundipharma shall take appropriate actions in order to enable Allos to commence a suit or take the actions set forth in the preceding sentence. If neither Mundipharma nor Allos commences a suit or takes action to enforce the PDX Patents, the PDX Licensor may elect to take such enforcement action.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party’s request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party’s comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which shall not be unreasonably withheld, conditioned or delayed. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Settlement.

(i) Mundipharma shall not settle any claim, suit or action that it brought under Section 8.4(b) in any manner that would negatively impact the applicable Allos Patents, Joint Patents or Mundipharma Patents or that would limit or restrict the ability of Allos to Develop, make, use, import, offer for sale, sell or otherwise Commercialize Products anywhere in the Field in the Allos Territory or to make or have made Products anywhere in the world, without the prior written consent of Allos, which consent shall not be unreasonably withheld, conditioned or delayed. Nothing in this Article 8 shall require Allos to consent to any settlement that is reasonably anticipated by Mundipharma to have a substantially adverse impact upon any Allos Patent, Joint Patent or Mundipharma Patent in the Allos Territory, or to the Development, Commercialization, use, importation, offer for sale or sale of Products in the Field in the Allos Territory, or to the manufacture of Products anywhere in the world.

(ii) Allos shall not settle any claim, suit or action that it brought under Section 8.4(b) in any manner that would negatively impact the applicable Allos Patents, Joint Patents or Mundipharma Patents or that would limit or restrict the ability of Mundipharma to Develop, make, use, import, offer for sale, sell or otherwise Commercialize Products anywhere in the Licensed Territory in the Field, without the prior written consent of Mundipharma, which consent shall not be unreasonably withheld, conditioned or delayed. Nothing in this Article 8 shall require Mundipharma to consent to any settlement that is reasonably anticipated by Mundipharma to have a substantially adverse impact upon any Allos Patent, Joint Patent or Mundipharma Patent in the Allos Territory, or to the Development, Commercialization, use, importation, offer for sale or sale of Products in the Licensed Territory in the Field.

(e) Expenses and Recoveries. The enforcing Party bringing a claim, suit or action under Section 8.4(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts shall be retained by the Party bringing suit, provided that, in the event Mundipharma is the Party bringing suit, such remaining amounts shall be deemed Net Sales and Mundipharma shall make a royalty payment to Allos with respect thereto in accordance with Section 7.4(a).

8.5 Patent Enforcement in the Allos Territory.

(a) Notification. If either Party becomes aware of any existing or threatened infringement of the Allos Patents, Joint Patents or Mundipharma Patents in the Field in the Allos Territory by a Third Party (“Allos Territory Infringement”), it shall promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Infringement.

(b) Enforcement Rights. For any Allos Territory Infringement, each Party shall share with the other Party all Information available to it regarding such actual or alleged infringement. Allos shall have the sole right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Allos Territory Infringement, at Allos’ cost and expense, if such Allos Territory Infringement involves only Allos Patents. As between the Parties, Allos shall have the first right, but not the obligation, to bring an appropriate
suit or other action against any person or entity engaged in such Allos Territory Infringement, at Allos cost and expense, if such Allos Territory Infringement involves Joint Patents or Mundipharma Patents. Allos shall have a period of ninety (90) days after its receipt or delivery of notice under Section 8.5(a) to elect to so enforce the Joint Patents or Mundipharma Patents against such Allos Territory Infringement (or to settle or otherwise secure the abatement of such Allos Territory Infringement). If Allos fails to commence a suit to enforce the applicable Joint Patents or Mundipharma Patents against such Allos Territory Infringement or to settle or otherwise secure the abatement of such Allos Territory Infringement within such period, then Mundipharma shall have the right, but not the obligation, to commence a suit or take action to enforce such Joint Patents or Mundipharma Patents against such Allos Territory Infringement at its own cost and expense. In this case, Allos shall take appropriate actions in order to enable Mundipharma to commence a suit or take the actions set forth in the preceding sentence. If neither Allos nor Mundipharma commences a suit or takes action to enforce the PDX Patents, the PDX Licensor may elect to take such enforcement action.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party’s request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party’s comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which shall not be unreasonably withheld, conditioned or delayed. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Settlement. Allos shall not settle any claim, suit or action that it brought under Section 8.5(b) in any manner that would negatively impact the applicable Joint Patents or Mundipharma Patents or that would limit or restrict the ability of Mundipharma to Develop, make, use, import, offer for sale, sell or otherwise Commercialize Products anywhere in the Licensed Territory, without the prior written consent of Mundipharma, which consent shall not be unreasonably withheld, conditioned or delayed. Nothing in this Article 8 shall require Mundipharma to consent to any settlement that is reasonably anticipated by Mundipharma to have a substantially adverse impact upon any Joint Patent or Mundipharma Patent, or to the Development, Commercialization, use, importation, offer for sale or sale of Products in the Licensed Territory.

(e) Expenses and Recoveries. The enforcing Party bringing a claim, suit or action under Section 8.5(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts shall be retained by the Party bringing suit.

8.6 PDX Patents. Each Party’s rights under this Article 8 with respect to the prosecution, maintenance and enforcement of any PDX Patent shall be subject to the rights of the PDX Licensor to prosecute, maintain and enforce such PDX Patent. Notwithstanding the foregoing, Allos shall provide Mundipharma reasonable opportunity to review and comment on prosecution efforts regarding the PDX Patents to the extent the PDX Licensor consents with Allos and provides Allos the right to review and comment on the same, in each case as is required pursuant to section 8.2 of the PDX License Agreement.

8.7 Infringement of Third Party Rights in the Licensed Territory. Subject to Article 10, if a Product used or sold by Mundipharma, its Affiliates or Sublicensees becomes the subject of a Third Party’s claim or assertion of infringement of a Patent granted by a jurisdiction within the Licensed Territory (each such claim or assertion a “Third Party Claim”), Mundipharma shall promptly notify Allos and the Parties shall agree on and enter into a common interest agreement, pursuant to which the Parties will agree to work toward their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the Third Party Claim and the appropriate course of action. Mundipharma shall be solely responsible for the defense of any such Third Party Claim, at Mundipharma’s cost and expense; provided that the provisions of Section 8.4 shall govern the right of Mundipharma to assert a counterclaim of infringement of any Allos Patents, Joint Patents or Mundipharma Patents against such Allos Territory Infringement (or to settle or otherwise secure the abatement of such Allos Territory Infringement). If Allos fails to commence a suit to enforce the applicable Joint Patents or Mundipharma Patents against such Allos Territory Infringement or to settle or otherwise secure the abatement of such Allos Territory Infringement within such period, then Mundipharma shall have the right, but not the obligation, to commence a suit or take action to enforce such Joint Patents or Mundipharma Patents against such Allos Territory Infringement at its own cost and expense. In this case, Allos shall take appropriate actions in order to enable Mundipharma to commence a suit or take the actions set forth in the preceding sentence. If neither Allos nor Mundipharma commences a suit or takes action to enforce the PDX Patents, the PDX Licensor may elect to take such enforcement action.

(a) Trademark License. Subject to the terms and conditions of this Agreement, Allos hereby grants to Mundipharma an exclusive, royalty-free right and license, with the right to sublicense solely as provided in Section 8.9(b), to use the trademarks set forth on Exhibit C (the “Licensed Marks”) solely in connection with the Commercialization of Products in the Field in the Licensed Territory.

(b) Sublicense Rights. Mundipharma shall have the right to grant sublicenses of the license granted in Section 8.9(a) solely to a Sublicensee that has received a sublicense from Mundipharma of the license granted to Mundipharma in Section 2.1(b). Such sublicense shall be included in the
applicable Mundipharma Sublicense Agreement, which shall obligate such Sublicensee to comply with the terms and conditions of Section 8.9(c) through 8.9(f), Section 8.9(h) and Section 8.9(j) as if such Sublicensee were Mundipharma.

(c) Ownership of the Licensed Marks. Mundipharma agrees and acknowledges that it has no interest, right, or title in the Licensed Marks other than the license granted in Section 8.9(a) and that it will not obtain any rights in or to the Licensed Marks.

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[ * ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

through its use in connection with the Products. Mundipharma further agrees that Allos is and will continue to be the sole and exclusive owner of all rights, title and interest in and to each Licensed Mark in any form or embodiment thereof and agrees that all goodwill associated with or attached to the Licensed Marks arising out of the use thereof by Mundipharma shall inure to the benefit of Allos.

(d) Registration; No Contest. Allos has registered, or has filed applications for registration of, the Licensed Marks in those countries and jurisdictions in the Licensed Territory indicated in Exhibit C. Upon the written request of Mundipharma, Allos will register or attempt to register the Licensed Marks in such other countries in the Licensed Territory in which Mundipharma reasonably expects to file a Drug Approval Application and seek to obtain Regulatory Approval. Mundipharma agrees that it will neither contest, oppose or challenge, nor assist any party in contesting, opposing or challenging, Allos’ ownership of the Licensed Marks or the distinctiveness or validity of the Licensed Marks. Mundipharma agrees that it will not at any time do or suffer to be done any act or thing that will in any way impair Allos’ ownership of or rights in and to the Licensed Marks or any registration thereof. Mundipharma will not register or attempt to register any Licensed Mark in any jurisdiction nor oppose Allos’ registration of any Licensed Mark, alone or with other words or designs, in any jurisdiction; provided, however, Mundipharma shall have the right to register as domain names the Licensed Marks in any country in the Licensed Territory using any country code domain names for such country, but specifically excluding the domain names set forth in the Letter Agreement. Mundipharma shall, on the reasonable request of Allos, give Allos or its authorized representative necessary information as to the use of the Licensed Marks pursuant to this Agreement which Allos may require and will render any assistance reasonably required by Allos in obtaining or maintaining the registrations of the Licensed Marks. Any costs incurred by Mundipharma in rendering such assistance shall be [*] and shall be [*].

(e) Compliance. The Licensed Marks may only be used on Products that are Commercialized in the Field in the Licensed Territory in accordance with applicable Law and current pharmaceutical industry standards of quality, including the terms of all applicable Regulatory Approvals.

(f) Use of the Licensed Marks. Mundipharma agrees to comply with all applicable Laws pertaining to the proper use and designation of the Licensed Marks. Additionally, Mundipharma shall:

(ii) use the Licensed Marks upon or in relation to the Products only in such manner that the distinctiveness, reputation, and validity of the Licensed Marks shall not be impaired. Without prejudice to the generality of the foregoing, Mundipharma shall use Reasonably Diligent Efforts to ensure in particular that each Licensed Mark is correctly spelled, is accompanied by words accurately describing the nature of the goods or services to which it relates, and is displayed as set forth in Exhibit C and that any text, graphics or designs adjacent to any Licensed Mark does not put the Licensed Mark or Allos in a negative or derogatory light;

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[ * ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(ii) comply with the reasonable requirements of Allos as to the form, manner, scale and context of use of the Licensed Marks, and the use of the statements to accompany them;

(iii) the first time Mundipharma plans to use a particular Licensed Mark, provide Allos with samples of the proposed packaging and related marketing and promotional materials to be used for the Products. Mundipharma shall consider in good faith any comments Allos may make regarding same;

(iv) display the proper form of trademark and service mark notice associated with the Licensed Marks in accordance with reasonable instructions received from Allos;

(v) include, on any item which bears a Licensed Mark, a statement identifying Allos as the owner of such Licensed Mark and stating that Mundipharma is an authorized user of such Licensed Mark;

(vi) not conduct, without the written consent of Allos, the whole or any part of its business under a business name or trading style which incorporates any of the Licensed Marks or which might materially impair the validity, reputation or distinctiveness of any of the Licensed Marks;
(vii) neither use nor display any of the Licensed Marks in such relation to any other mark or marks owned by any Third Party or Mundipharma so as to suggest that the multiple marks constitute a single or composite trademark, service mark, or are under the same proprietorship.

(g) Out-of-Pocket Costs. All out-of-pocket expenses incurred by Allos in connection with pursuit of registration and maintenance of registered Licensed Marks in the Licensed Territory during the Term, including in connection with filing of necessary maintenance and use documents, applying for renewal, and payment of any required taxes or fees due in connection with such applications or registrations, shall be [*] and shall be [*].

(h) Quality Control. The nature and quality of the Products, and all advertising and promotional uses of the Licensed Marks by Mundipharma, shall conform to or exceed industry standards for products similar to the Products. Mundipharma shall, and shall at the request of Allos or its authorized representative, furnish at Mundipharma’s expense such samples of the Products for inspection and analysis as may reasonably be requested.

(i) Enforcement of Licensed Marks.

(A) If either Party or its Affiliate becomes aware of actual or threatened infringement in the Licensed Territory of any Licensed Mark or of a mark or name confusingly similar to any Licensed Mark, such Party shall promptly notify the other Party in writing. Mundipharma shall have the first right, but not the obligation, to bring infringement or unfair competition actions in the Licensed Territory involving a Licensed Mark. Allos shall, at the request and expense of Mundipharma, cooperate and provide reasonable assistance in any

[j] Third Party Trademark Litigation. In the event of the initiation of any suit by a Third Party against Mundipharma for trademark infringement involving Commercialization of Products in the Field in the Licensed Territory, Mundipharma shall promptly notify Allos in writing. Mundipharma shall have the right, but not the obligation, to defend such suit at its expense.

(k) Alternative Trademark. If (x) any of the events set forth in Section 12.5(i)-(vi) shall have occurred with respect to Allos, (y) a Regulatory Authority in any country in the Licensed Territory refuses to permit Mundipharma to use a Licensed Mark in connection with the Commercialization of Products in such country, or a Licensed Mark is found by a court of competent jurisdiction to infringe Third Party rights in such country, or (z) if Mundipharma determines in good faith that such Licensed Mark is not commercially viable in any country in the Licensed Territory and Allos reasonably agrees in writing (not to be unreasonably withheld, conditioned or delayed), then Mundipharma may use an alternative trademark owned by Mundipharma and approved by the JSC, in lieu of such Licensed Mark, in connection with the Commercialization of Products in such country.

(l) Assignment. Allos hereby transfers and assigns to Mundipharma, its successors and assigns, Allos’ entire ownership interest and title in the trademark [*], for use in connection with Commercializing Products in the Field in the Licensed Territory, together with any and all goodwill assigned therewith, to be held and enjoyed by Mundipharma, its successors and assigns, to the full end of the term thereof, as may be extended by Law as fully and entirely as the same would have been held and enjoyed by Allos if this transfer and assignment had not been made. From and after the Effective Date, Mundipharma shall pay all of the out-of-pocket costs and expenses associated with registering and maintaining the [*] trademark in the Licensed Territory. The Parties agree to execute and deliver, within [*] days after the Effective Date, a trademark assignment agreement (or confirmation of trademark assignment) reflecting the terms set forth in this Section 8.9(l).
9.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated;

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to enforcement of remedies under applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies;

(c) No Conflict. To such Party’s Knowledge, the execution and delivery of this Agreement, the performance of such Party’s obligations in the conduct of the Development Plan and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Law existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation or by-laws of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a material default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date;

(d) Other Rights. Neither Party nor any of their respective Affiliates is a party to or otherwise bound by any oral or written contract or agreement, other than the PDX License Agreement (only as it relates to Allos), that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of such Party’s rights under this Agreement;

(e) No Violation. Neither Party nor any of their respective Affiliates is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of such Party’s obligations hereunder; and

(f) No Debarment. As of the Effective Date, none of such Party’s employees or consultants:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority;

(ii) has, to such Party’s Knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. health care programs (or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

9.2 Additional Representations and Warranties of Allos. Allos represents and warrants to Mundipharma as follows, as of the Effective Date:

(a) Title; Encumbrances. It has (i) sufficient legal and/or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges or claims of any kind, of or to the Allos Technology, the Allos Manufacturing Know-How or the Allos ISS Technology to grant the licenses to Mundipharma as purported to be granted pursuant to this Agreement; and (ii) to Allos' Knowledge, no Third Party (other than the PDX Licensee) has taken any action before the United States Patent and Trademark Office, or any counterpart thereof outside the U.S., claiming legal and/or beneficial ownership of or license to any
of the Allos Patents;

(b) PDX License Agreement. Allos is not in material breach of the PDX License Agreement, and has not received any notices from the PDX Licensor of any breaches of the PDX License Agreement within the last three (3) years;

(c) Notice of Infringement or Misappropriation. It has not received any written notice from any Third Party asserting or alleging that (i) any research, Development, manufacture or Commercialization of the Product by Allos prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the exercise of Mundipharma’s rights granted under this Agreement infringes or would infringe any Third Party intellectual property rights;

(d) Non-Infringement of Third Party Rights. To Allos’ Knowledge, the Development, manufacture and Commercialization of the Product can be carried out in the manner reasonably contemplated as of the Effective Date without infringing any issued patents owned or controlled by a Third Party;

(e) Non-Infringement of Rights by Third Parties. To Allos’ Knowledge, no Third Party is infringing or has infringed the Allos Technology or the Allos ISS Technology or is misappropriating the Allos Manufacturing Know-How existing as of the Effective Date;

(f) Non-Assertion by Third Parties. To Allos’ Knowledge, no Third Party has asserted in writing that the issued patents within the Allos Patents set forth in Schedule 1 are invalid or unenforceable in the Licensed Territory or the Allos Territory;

(g) No Proceeding. There are no pending, and to Allos’ Knowledge, no threatened, adverse actions, claims, investigations, suits or proceedings against Allos or any of its Affiliates, at Law or in equity, or before or by any Governmental Authority, involving the Allos Technology or the Product, nor to Allos’ Knowledge has any such adverse action, claim, investigation, suit or proceeding been brought or threatened during the past three (3) years, in each case, which has been resolved in a manner that materially impairs any of Allos’ rights in and to any such Allos Technology or to the Product;

(h) No Consents. No authorization, consent, approval of a Third Party, other than the PDX Licensor, nor to Allos’ Knowledge, any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution and delivery of this Agreement by Allos; (ii) the consummation by Allos of the transactions contemplated hereby; or (iii) prevention of the termination of any right, privilege, license or agreement relating to the Allos Technology or the continuation thereof following the Effective Date;

(i) No Non-Competition Agreements. Neither Allos nor any of its Affiliates are bound by any non-competition agreements related to the Product;

(j) Compliance with Laws. To Allos’ Knowledge, Allos has complied with all applicable Laws in connection with Allos’ prosecution of the Allos Patents other than the PDX Patents, including the duty of candor owed to any patent office pursuant to such Laws;

(k) No Grant of Rights. Allos has not granted any rights with respect to the Product, the Allos Technology, the Allos Manufacturing Know-How and/or the Allos ISS Technology in the Licensed Territory, in each case, to any person or entity other than Mundipharma, except pursuant to the PDX License Agreement or contracts with Third Parties in connection with, and for the purpose of, the development and/or manufacture of the Product for or on behalf of Allos and in connection with any named patient supply program;

(l) No Unauthorized Use. Neither Allos nor any of its Affiliates has received any written notice of any unauthorized use, infringement, misappropriation, or dilution by any person, including any current or former employee or consultant of Allos or its Affiliates, of the Product or of any of the Allos Technology, the Allos Manufacturing Know-How or the

[ * ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Allos ISS Technology, except as would not materially adversely affect the rights granted to Mundipharma under this Agreement;

(m) Intellectual Property Rights. The Allos Technology, the Allos Manufacturing Know-How and the Allos ISS Technology includes all intellectual property rights Controlled by Allos which are reasonably necessary for the Development and Commercialization of the Product by Mundipharma in accordance with the terms of this Agreement as contemplated on the Effective Date;
(n) Allos Patents and Patent Applications. (i) The Allos Patents listed on Schedule 1 are the only patents and patent applications relating to the Product, including the use and methods of manufacture of the Product, in which Allos has an interest either alone or jointly with any Third Party, and (ii) Allos does not have Knowledge of any Information which leads it to believe that any issued patents included in the Allos Patents are invalid or unenforceable;

(o) Renewal and Maintenance Fees. To Allos' Knowledge, all material renewal and maintenance fees due as of the Effective Date with respect to the prosecution and maintenance of the Allos Patents have been paid;

(p) Access to Information. Allos has, when requested by Mundipharma to conduct its due diligence review, allowed Mundipharma access to all material information in Allos' possession or control (i) containing the results of all preclinical testing and clinical testing of the Product; (ii) concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof with respect to the Product; and (iii) in respect of the Allos Technology and the Product;

(q) Inventors. To Allos' Knowledge, the inventors named in the Allos Patents (excluding the PDX Patents) are all of the true inventors for such Allos Patents and each of such inventors has assigned, or is under a written obligation to assign, to Allos or its Affiliates all of his or her right, title and interest to such Allos Patents (excluding the PDX Patents) and the inventions described therein;

(r) Employee Confidentiality Agreements. All current and former employees and paid consultants (in the case of academic consultants, those acting outside the scope of their academic affiliation) of Allos and its Affiliates who are or have been substantively involved in the conception, design, review, evaluation, reduction to practice, or development of Allos Technology (excluding the Allos Technology licensed to Allos under the PDX License Agreement) or the Product have executed written contracts or are otherwise obligated to protect the confidential status and value thereof and to vest in Allos exclusive ownership of the Allos Technology (excluding the Allos Technology licensed to Allos under the PDX License Agreement) and the Product;

(s) Third Party Confidentiality. To Allos' Knowledge, no Third Party has any Allos Know-How or Allos Manufacturing Know-How in its possession or control which is not subject to continuing obligations of confidentiality owed to Allos or its Affiliates (except to the extent that Section 11.1(a), (b), (c), (d) or (e) applies) for at least the duration of the term set forth in confidentiality agreements (or other agreements containing confidentiality provisions) between Allos and such Third Party;

(t) Provision of Primary Agreements. Allos has, when requested by Mundipharma to conduct its due diligence review, allowed Mundipharma access to all material license agreements, service agreements, master services agreements, clinical trial agreements, supply agreements, distribution agreements, and substantially similar agreements to which Allos is a party (each, a “Primary Agreement”), and all related amendments and project addenda or work orders (to the extent the terms of such project addenda or work orders control the corresponding terms of a Primary Agreement), that, to Allos' Knowledge, relate to (i) the ownership of the Allos Technology, (ii) conducting clinical studies and regulatory activities (e.g., preparation of regulatory applications) that are necessary or useful to obtain and maintain Drug Approval of the Product, and (iii) the manufacture, supply and distribution of Raw Materials, API and Bulk Product (as each such term is defined in the Supply Agreement).

(u) Clinical Data. All clinical data submitted (or intended for submission) in support of the DAA filed by Allos and validated by the EMA on December 15, 2010 was generated pursuant to the clinical trial agreements set forth in Schedule 2;

(v) Safety and Efficacy. Allos has informed Mundipharma of all adverse drug reactions known to Allos relating to the Product or its use and Allos has not received any written communication from any Regulatory Authority raising questions concerning the safety or efficacy of the Product (including any of its ingredients);

(w) Good Practices. To Allos' Knowledge, GLP, GCP and GMP (as applicable) have been followed in all material respects in the Development and manufacture of the Product;

(x) Allos Improvements/New Technology.

(i) There are no “Allos Improvements” (other than the Allos Patents, Allos Know-How and Allos Manufacturing Know-How) or “New Technology” (as such terms are defined in the PDX License Agreement) under the PDX License Agreement; and

(ii) All Allos Manufacturing Know-How used by [ * ] and/or [ * ] for the manufacture of API (as defined in the Supply Agreement) and/or Bulk Product is owned exclusively by Allos;

(y) Regulatory Matters.
(i) Allos has provided or made available, when requested by Mundipharma to conduct its due diligence review, any and all documents and communications in its possession from and to any Governmental Authority, or prepared by any Governmental Authority, related to the Product, that may bear on the Conditional Approval or compliance with the requirements of any Governmental Authority, including any notice of inspection, inspection report, warning letter, deficiency letter, or similar communication;

(ii) Neither Allos nor any of its Affiliates has received, with respect to the Product, written communication (including any warning letter, untitled letter, or similar notices) from any Governmental Authority and, to Allos’ Knowledge, there is no action pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that with respect to the Product, Allos or any of its Affiliates is not currently materially in compliance with any and all applicable Laws implemented by such Governmental Authority. Neither Allos nor any of its Affiliates has received any written notice from any Governmental Authority claiming that the research, development, manufacture, use, offer for sale, sale, or import of the Product is not in material compliance with all applicable Laws and permits; and

(iii) To Allos’ Knowledge, none of Allos, any of its Affiliates or any of their respective officers, employees or agents has made, with respect to the Product, an untrue statement of a material fact to any Governmental Authority or failed to disclose a material fact required to be disclosed to such Governmental Authority; and

(c) New Compound. Allos is not developing any New Compound.

9.3 Additional Representations and Warranties of Mundipharma. Mundipharma represents and warrants to Allos as follows, as of the Effective Date:

(a) Ability to Perform. Mundipharma has the liquidity to meet and comply with its foreseeable payment obligations under this Agreement and it has sufficient resources to perform (or have performed on its behalf) all of its obligations and activities, including all of its Development, Commercialization and diligence obligations, as applicable, under this Agreement.

9.4 Covenants.

(a) No Debarment. In the course of the Development and Commercialization of the Product, neither Party shall utilize any employee or consultant:

(i) who has been debarred under Section 306(a) or 306(b) of the FD&C Act or pursuant to the analogous Laws of any Regulatory Authority;

(ii) who, to such Party’s Knowledge, has been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or otherwise pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority, during the employee’s or consultant’s employment or contract term with such Party; and

(iii) who is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. health care programs (or who has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

(b) Each Party shall notify the other Party promptly, but in no event later than five (5) business days, upon becoming aware that any of its employees or consultants has been excluded, debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by any Regulatory Authority.

(c) Conduct of Activities. Each Party shall use Reasonably Diligent Efforts to conduct Development of the Product in a manner consistent with the following: (i) in the case of Mundipharma, not materially adversely impacting Allos’ or its Affiliates’ or Third Party partner’s Development or Commercialization efforts for the Product in the Field in the Allos Territory; and (ii) in the case of Allos, not materially adversely impacting Mundipharma’s or its Affiliates’ or Sublicensees’ Development or Commercialization efforts for the Product in the Field in the Licensed Territory;
(d) Compliance. Each Party and its Affiliates shall comply in all material respects with all applicable Laws in the Development and Commercialization of the Product and the performance of its obligations under this Agreement, including where applicable the statutes, regulations and written directives of the FDA, Health Canada, the EMA and any Regulatory Authority having jurisdiction in the Licensed Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time and each to the extent applicable;

(e) Inventors. If and to the extent required by applicable Law, each Party shall be responsible to reimburse the inventors named in such Party’s Patents;

(f) No Violation. Neither Party nor any of its Affiliates will enter into or otherwise have any obligation to any person or entity, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of such Party’s obligations hereunder;

(g) Third Party Confidentiality. Each Party shall maintain the confidentiality of the Allos Know-How, Allos Manufacturing Know-How and the Mundipharma Know-How, and shall ensure that no Third Party has any Allos Know-How, Allos Manufacturing Know-How or Mundipharma Know-How in its possession or control which is not subject to continuing obligations of confidentiality owed to such Party or its Affiliates pursuant to the terms of agreements containing confidentiality provisions, except to the extent that Section 11.1(a), (b), (c), (d) or (e) applies to such Allos Know-How, Allos Manufacturing Know-How or Mundipharma Know-How;

(h) Performance under the PDX License Agreement. Except if a breach by Allos of the PDX License Agreement is due to Mundipharma’s breach of this Agreement, Allos shall continue to fulfill its obligations under the PDX License Agreement and covenants that it shall not materially breach the PDX License Agreement. Allos shall notify Mundipharma, within [*] of the following occurrences: (i) its receipt from the PDX Licensor of written notice of any material breach or potential material breach by Allos under the PDX License Agreement;

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or (ii) any disputes it has with the PDX Licensor pursuant to Section 13 of the PDX License Agreement;

(i) New Technology. Allos shall notify Mundipharma if it is offered or it acquires any “New Technology” under the PDX License Agreement;

(j) Performance under Agreements with Current Third Party Manufacturers. Allos shall fulfill its obligations under its agreements with its Current Third Party Manufacturers and covenants that it shall not materially breach such agreements. Allos shall notify Mundipharma within [*] of its receipt of written notice from any Current Third Party Manufacturer of any material breach or potential material breach by Allos under its agreement with such Current Third Party Manufacturer;

(k) MMCO Affiliate. Mundipharma represents and covenants that MMCO is, as of the Effective Date, and shall at all times during the Term remain, an Affiliate of Mundipharma, provided, however, that if MMCO (or its permitted Affiliate assignee) is no longer an Affiliate of Mundipharma, MMCO (or its permitted Affiliate assignee) shall transfer any rights and obligations relating to this Agreement or the Supply Agreement to another Affiliate of Mundipharma.

(l) Right of First Negotiation. In the event that Allos Controls a New Compound and desires to enter into a license or other arrangement with a Third Party during the Term pursuant to which the Third Party would receive rights to develop and/or commercialize such New Compound in the Licensed Territory in [*] or [*] pursuant to this Agreement as of such time, Allos shall promptly notify Mundipharma in writing. If within [*] of receiving such notice from Allos, Mundipharma notifies Allos in writing that it wishes to negotiate a license to the New Compound, Allos shall, within [*] of such notice from Mundipharma, submit information to Mundipharma on such New Compound, including any final study reports of the pre-clinical and clinical trials of the New Compound conducted by or on behalf of Allos or its Affiliates, and [*] and upon financial and other terms acceptable to the Parties. The Parties shall negotiate such offer in good faith for a period of [*] from the date the offer is received by Mundipharma. If the Parties reach agreement on the terms of such a license, the Parties shall execute a new license agreement setting out such terms. If, at the end of the [*], Allos and Mundipharma are unable to reach agreement on such development and/or commercialization rights, Allos shall be free to grant a license or enter into any other arrangement with a Third Party to develop and/or commercialize such New Compound and Allos shall have no further obligation to Mundipharma with respect to such New Compound. Allos shall not enter into any discussions or negotiations with a Third Party concerning the New Compound in the Licensed Territory until the New Compound has been offered to Mundipharma pursuant to this Section 9.4(m) and the [*] period has expired without the Parties reaching agreement.
ARTICLE 10

INDEMNIFICATION

10.1 Indemnification by Allos. Allos shall, at its sole expense, defend, indemnify, and hold Mundipharma and its Affiliates and their respective officers, directors, employees, and agents (the "Allos Indemnitees") harmless from and against any and all Third Party claims, suits, proceedings, damages, losses, liabilities, costs, expenses (including court costs and reasonable attorneys’ fees and expenses) and recoveries (collectively, “Claims”) to the extent that such Claims arise out of, are based on, or result from (a) Development of the Product by or on behalf of Allos or its Affiliates or its or their sublicensees (other than Mundipharma and its Affiliates) prior to the Effective Date, or after the Effective Date pursuant to an Incremental Study for which Allos is the Conducting Party or pursuant to an Allos Study, (b) Commercialization of the Product by or on behalf of Allos or its Affiliates or its or their sublicensees (other than Mundipharma and its Affiliates), (c) the breach of any of Allos’ obligations under this Agreement, including Allos’ representations and warranties, covenants and agreements set forth herein, or (d) the willful misconduct or negligent acts of Allos, its Affiliates, or the officers, directors, employees, or agents of Allos or its Affiliates. The foregoing indemnity obligation shall not apply (i) to the extent that (x) the Mundipharma Indemnitees fail to comply with the indemnification procedures set forth in Section 10.4 and Allos’ defense of the relevant Claims is prejudiced by such failure or (y) such Claims arise out of or result from the gross negligence or willful misconduct of Mundipharma or its Affiliates, or any related breach by Mundipharma of its representations, warranties and/or covenants hereunder; or (ii) to Claims for which Mundipharma has an obligation to indemnify Allos pursuant to Section 10.2, as to which Claims each Party shall indemnify the other to the extent of its respective liability for such Claims.

10.2 Indemnification by Mundipharma. Mundipharma shall, at its sole expense, defend, indemnify, and hold Allos and its Affiliates and their respective officers, directors, employees, and agents (the "Mundipharma Indemnitees") harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) Development of the Product by or on behalf of Mundipharma or its Affiliates or its or their Sublicensees pursuant to an Incremental Study for which Mundipharma is the Conducting Party, (b) Commercialization of the Product by or on behalf of Mundipharma or its Affiliates or its or their Sublicensees, (c) the breach of any of Mundipharma’s obligations under this Agreement, including Mundipharma’s representations and warranties, covenants and agreements set forth herein, or (d) the willful misconduct or negligent acts of Mundipharma, its Affiliates, or the officers, directors,
Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 10.

10.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10.1 OR 10.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

10.6 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, or shall self-insure, in each case in a manner adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested or commercially distributed or sold by such Party. Each Party shall procure insurance or self-insure at its own expense, except for clinical trial insurance specifically obtained for any Shared Study, the costs of which shall be included in Joint Development Costs. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this Article 10. Each Party shall provide the other Party with written evidence of such insurance or self-insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance.

ARTICLE 11
CONFIDENTIALITY

11.1 Confidentiality. Each Party agrees that, during the Term and for a period of five (5) years thereafter, it and its Affiliates shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement or the Supply Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it or its Affiliate by the other Party or its Affiliate pursuant to this Agreement or the Supply Agreement, except to the extent expressly authorized by this Agreement or the Supply Agreement or as otherwise agreed to in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party’s Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party or its Affiliate;
(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party or its Affiliate;

11.2 Security Procedures. Each Party shall take reasonable steps to prevent disclosure of its Confidential Information to unauthorized persons or use thereof for any purpose other than as permitted hereunder. Each Party shall require its Affiliates and employees to comply with the terms of this Agreement and shall be responsible for the acts or omissions of its Affiliates and employees.

11.3 Remedies. In addition to any other right or remedy provided by law or in this Agreement, the receiving Party may seek and be entitled to an injunction, and any other relief that a court may grant, to prevent any breach or threatened breach of this Agreement. Each Party waives any claim that it has for damages in connection with any such breach or threatened breach of this Agreement.
11.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 11.1, a Party or its Affiliate may disclose the other Party’s Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated by this Agreement or the Supply Agreement; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of the Product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement or the Supply Agreement;

(b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement or the Supply Agreement; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use having a minimum term of five (5) years; or

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or other order.

Notwithstanding the foregoing, in the event a Party or its Affiliate is required to make a disclosure of the other Party’s Confidential Information pursuant to Section 11.2(a) or 11.2(d), such Party shall promptly notify the other Party of such required disclosure and, upon the other Party’s request, such Party and its Affiliates shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

11.3 Technical Publication. All publications, and other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement or otherwise relating to the Product (each of the foregoing, a “Publication”) shall comply with the strategy established by the JDC pursuant to Section 3.2(a)(vi). Neither Party nor their Affiliates may submit for publication, publish or present a Publication without the opportunity for prior review by the other Party, except to the extent required by applicable Laws. A Party seeking, or whose Affiliate is seeking, to submit, publish or present a Publication shall provide the other Party the opportunity to review and comment on the proposed Publication at least fifteen (15) days prior to its intended submission for publication or presentation. The other Party shall provide the Party seeking, or whose Affiliate is seeking, to publish or present its comments in writing, if any, within ten (10) days after receipt of such proposed Publication. The Party seeking, or whose Affiliate is seeking, to publish or present shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party’s request to remove any and all of such other Party’s Confidential Information from the proposed Publication, provided such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement or the Supply Agreement; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement.

11.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 11.4.

(b) The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit B, which shall be issued on or promptly after the Effective Date.

(c) After release of such press release, if either Party or its Affiliate desires to make a public announcement concerning the material terms of this Agreement, or any clinical or regulatory announcements, such Party shall give reasonable prior advance notice of the proposed text of such
11.4 Exclusive Property. All Confidential Information is the sole and exclusive property of the disclosing Party and the permitted use thereof by the revealing Party for purposes of its performance hereunder will not be deemed a license or other right of the receiving Party to use any such Confidential Information for any other purpose.
the Royalty Term for a Product in a particular country, the licenses granted by Allos to Mundipharma under Sections 2.1(a) and 2.1(b) in such country shall become fully-paid and royalty free and, except for the sublicenses granted thereunder to the Allos Technology licensed to Allos under the PDX License Agreement, such licenses shall remain exclusive. Upon the expiration of the Royalty Term for a Product in a particular country pursuant to Section 7.4(b)(i) or Section 7.4(b)(iii), the sublicenses granted under Sections 2.1(a) and 2.1(b) to the Allos Technology licensed to Allos under the PDX License Agreement in such country shall become non-exclusive.

12.2 Termination for Breach. Each Party (the “Non-Breaching Party”) shall have the right to terminate this Agreement in its entirety or on a country-by-country basis immediately upon written notice to the other Party (the “Breaching Party”) if the Breaching Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail (a “Default Notice”), fails to cure such material breach within [*] after delivery of the Default Notice (or within [*] after delivery of the Default Notice in the event such material breach is solely based on the Breaching Party’s failure to pay any amounts due hereunder). For the avoidance of doubt, in addition to any other failure to pay any amounts due hereunder, failure by either Party to pay any portion of its Joint Development Costs under this Agreement shall constitute a material breach of such non-paying Party’s obligations under this Agreement.

12.3 Termination for Patent Challenge. Mundipharma will provide written notice to Allos at least [*] prior to Mundipharma or its Affiliates or Sublicensees (individually or in association with any other person or entity) bringing an action to challenge the validity, enforceability or scope of any Allos Patents or Joint Patents anywhere in the world. In the event that Mundipharma or its Affiliates or Sublicensees (individually or in association with any other person or entity) brings an action to challenge the validity, enforceability or scope of any Allos Patents or Joint Patents anywhere in the world, Allos shall have the right to terminate this Agreement in its entirety immediately upon written notice to Mundipharma.

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

12.4 Unilateral Termination by Mundipharma.

(a) Termination Upon Written Notice; Change of Control of Allos.

(i) Notwithstanding any other provision of this Agreement, Mundipharma may terminate this Agreement in its entirety upon [*] prior written notice to Allos at any time.

(ii) Notwithstanding the provisions of subclause (i) above, promptly, but no later than [*] after the completion of any Change of Control of Allos, Allos shall provide written notice of the same to Mundipharma (an “Allos Change of Control Notice”). If Mundipharma elects to terminate this Agreement as a result of such Change of Control of Allos, Mundipharma shall provide [*] prior written notice of termination to Allos no later than [*] after delivery of the Allos Change of Control Notice and, in the absence of such notice of termination within [*] after the Allos Change of Control Notice, this Agreement will remain in full force and effect. For the avoidance of doubt, the provisions of this Section 12.4(a)(ii) shall in no way impact Mundipharma’s right in Section 12.4(a)(i) to terminate this Agreement at any time upon [*] prior written notice to Allos.

(b) Termination by Regulatory Authority. Should any serious and unexpected events or issues occur with respect to the safety of any Product as a result of which (i) Regulatory Approval for such Product is terminated or suspended in one or more regulatory jurisdictions in the Licensed Territory, or (ii) a Regulatory Authority directs or requests discontinuance of development, use or sale of such Product in one or more countries in the Licensed Territory, then Mundipharma’s obligations under this Agreement with respect to such Product will be suspended in such regulatory jurisdiction(s) and/or country(ies) (as applicable) until such serious safety event is resolved and Regulatory Approval for such Product is no longer terminated or suspended or the Regulatory Authority has given approval again to distribute or sell such Product (as applicable) in such regulatory jurisdiction(s) and/or country(ies). Mundipharma may, upon written notice to Allos, terminate this Agreement pursuant to this Section 12.4(b) if Mundipharma’s obligations under this Agreement are suspended pursuant to this Section 12.4(b) for a period in excess of twelve (12) months.

(c) Breach or Termination of PDX License Agreement.

(i) Within [*] of receiving written notice from the PDX Licensor that Allos is in material breach of the PDX License Agreement (a “PDX Breach”), Allos shall provide Mundipharma with written notice of such PDX Breach. To the extent that Allos is unable or unwilling to cure the PDX Breach within the applicable cure period, and provided that Allos does not dispute the PDX Breach within the applicable cure period, the Parties hereby agree that Mundipharma shall have the right, but not the obligation, to cure such PDX Breach (or cause such PDX Breach to be cured) on behalf of Allos. To the extent that Allos disputes the PDX Breach, Mundipharma will not proceed to cure or cause such PDX Breach to be cured in accordance with this Section 12.4(c)(i) unless and until Allos is unsuccessful in defending against such PDX Breach. In the event Mundipharma proceeds to cure or causes such PDX Breach to be cured on behalf of Allos in accordance with this Section 12.4(c)(i), any payments
12.5 Termination for Bankruptcy. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party (i) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (ii) makes a general assignment for the benefit of its creditors, (iii) commences a voluntary case under the Bankruptcy Code, (iv) files a petition seeking to take advantage of any applicable Laws relating to bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, (v) has a proceeding or case commenced against it in any court of competent jurisdiction (which proceeding or case is not discharged within sixty (60) days of the filing thereof), seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of all or any substantial part of its assets, or (C) similar relief under the Bankruptcy Code, or an order, judgment or decree approving any of the foregoing is entered and continues unstayed for a period of sixty (60) days, or (vi) has an order for relief against it entered in an involuntary case under the Bankruptcy Code.

12.6 Effect of Termination.

(a) Upon the early termination of this Agreement pursuant to Sections 12.2 (except as otherwise provided in Section 12.6(c)), 12.3, 12.4 (other than Section 12.4(c)(iii)) or 12.5, all licenses granted to Mundipharma under Section 2.1 shall terminate throughout the Licensed Territory (save to the extent required to enable Mundipharma to sell its inventory of Product which Allos does not purchase pursuant to Section 12.6(a)(v)) and the following shall apply (in addition to any other rights and obligations under this Agreement with respect to such termination):

(i) Regulatory Materials; Data; Domain Names. To the extent permitted by applicable Laws, Mundipharma shall transfer and assign to Allos: (A) all Regulatory Materials, Regulatory Approvals, and related data relating to the Product throughout the Licensed Territory, except for Incremental Studies where Mundipharma is the Conducting Party and Allos has not exercised its Opt-In Right referred to in Section 4.4(c)(v)); (B) all domain names registered by Mundipharma in accordance with Section 8.9(d), and, in connection with the preceding, Mundipharma shall cooperate as reasonably requested by Allos to effect such transfer on the applicable domain name registries.

(ii) Mundipharma License. Mundipharma hereby grants to Allos, effective upon such termination, a non-exclusive, fully paid, royalty-free, irrevocable license (with the right to grant sublicenses through multiple tiers), under the Mundipharma Technology, to Develop, make, have made, use, sell, offer for sale, import and otherwise Commercialize the Products throughout the Licensed Territory.

(iii) Transition Assistance. Mundipharma shall provide such reasonable assistance as may be reasonably necessary or useful for Allos to continue activities Mundipharma is then performing or having performed, including assigning or amending as appropriate, upon request of Allos, any agreements or arrangements with Third Party vendors to Develop, distribute, sell or otherwise Commercialize the Product. To the extent that any such contract between Mundipharma and a Third Party is not assignable to Allos, Mundipharma shall reasonably cooperate with Allos to arrange to continue to provide such services for a reasonable time after termination.

(iv) Ongoing Joint Development Costs. Mundipharma shall continue to be responsible for the Mundipharma Share (at the current rate pursuant to Section 4.5) of Joint Development Costs incurred pursuant to the Development Plan during the [*] period after the effective date of termination of this Agreement. Notwithstanding the foregoing, if Mundipharma elects to terminate this Agreement pursuant to (A) Section 12.2, Mundipharma shall not be responsible for the Mundipharma Share of Joint Development Costs incurred during the [*] period after the effective date of such termination of this Agreement by Mundipharma, or (B) Section 12.4(a)(ii) due to a Change of Control of Allos, and provided that Mundipharma delivers written notice of termination under Section 12.4(a)(ii) within [*] of delivery of the Allos Change of Control Notice, Mundipharma shall not be responsible for the Mundipharma Share of Joint Development Costs incurred during the [*] period after the effective date of such termination of this Agreement by Mundipharma.

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Allos shall not take any actions or make any omissions to prevent Mundipharma therefrom; to all Product in the Licensed Territory, as reconveyed and released pursuant to this Section 12.6(b)(i) in the Licensed Territory as it may see fit, survive such termination, including any audit, payment and record retention provisions. Mundipharma will thereafter be free to exercise its rights Reimbursement Amount). Such other provisions hereof as are necessary to administer the calculation and payment of such royalties will also survive such termination; and

(c) Upon the early termination of this Agreement by Mundipharma pursuant to Section 12.4(c)(ii), Mundipharma may choose, in its sole discretion, (x) to take those actions and permit Allos to exercise those rights set forth in Section 12.6(a)(i), (iii), (v) and (vi), or (y) have any or all of the following apply and, in the event that Mundipharma elects to have the following apply, the following shall be Mundipharma’s sole and exclusive remedy for or relating to Mundipharma’s termination of this Agreement pursuant to Section 12.4(c)(ii):

(i) Transfer to Mundipharma. All of Mundipharma’s rights under Section 2.1 of this Agreement shall continue, and Mundipharma shall require that Allos promptly takes, and Allos hereby agrees to take, such actions as Mundipharma may reasonably request, in order to transfer to Mundipharma or its Affiliates or Sublicensees, free of charge, in respect of the Licensed Territory only, all of the rights, title and interest retained by Allos pursuant to Section 2.1(e). In the event of such an assignment, Allos will, at its expense and at Mundipharma’s request, deliver, execute and/or deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and take or cause to be taken all such actions as may be reasonably necessary to effectuate such transfer. Allos will further reconvey and release to Mundipharma all rights and privileges originally granted to Allos by Mundipharma under this Agreement (including those granted under Section 8.9), including those co-exclusive rights, such that all such rights and privileges will vest exclusively with Mundipharma. Mundipharma will, in such circumstances not be required to pay any further milestones required under Section 7.3 of this Agreement, but shall pay to Allos the royalties on all Net Sales of Products in the Licensed Territory set forth in Section 7.4, after deducting (A) royalty payments made to the PDX Licensor (with respect to the same Net Sales) in accordance with Mundipharma’s assumption of the rights and responsibilities of the PDX License Agreement pursuant to Section 12.6(b)(iii); and (B) [*] of Mundipharma’s costs (if any) of curing the consequences of Allos’ breach or actions that resulted in termination under Section 12.4(c)(ii) (such costs do not, for the avoidance of doubt, include the Allos Unpaid Reimbursement Amount). Such other provisions hereof as are necessary to administer the calculation and payment of such royalties will also survive such termination, including any audit, payment and record retention provisions. Mundipharma will thereupon be free to exercise its rights to all Product in the Licensed Territory, as reconveyed and released pursuant to this Section 12.6(b)(i) in the Licensed Territory as it may see fit, and Allos will not take any actions or make any omissions to prevent Mundipharma therefrom;

(ii) Transition Assistance. Allos shall provide such reasonable assistance, at no cost to Mundipharma, as may be reasonably necessary or useful for Mundipharma to continue Developing the Product throughout the Licensed Territory to the extent Allos is then performing or having performed such activities, including assigning or amending as appropriate, upon request of Mundipharma, any agreements or arrangements with Third Party vendors to Develop the Product. To the extent that any such contract between Allos and a Third Party is not assignable to Mundipharma, Allos shall reasonably cooperate with Mundipharma to arrange to continue to provide such services for a reasonable time after termination; and

(iii) Assumption of PDX License Agreement. Provided that Mundipharma is not in breach of this Agreement at the time the PDX License Agreement terminates, in exercising its rights under Section 12.6(b)(i), Mundipharma will assume all rights and responsibilities of Allos under the PDX License Agreement, including the royalties, milestones and sublicense fees provisions [*], to the extent applicable to the rights granted to Mundipharma under this Agreement (i.e., in respect of the Licensed Territory only).

(b) Upon the early termination of this Agreement by Mundipharma pursuant to Section 12.4(c)(ii), Mundipharma may choose, in its sole discretion, (x) to take those actions and permit Allos to exercise those rights set forth in Section 12.6(a)(i), (iii), (v) and (vi), or (y) have any or all of the following apply and, in the event that Mundipharma elects to have the following apply, the following shall be Mundipharma’s sole and exclusive remedy for or relating to Mundipharma’s termination of this Agreement pursuant to Section 12.4(c)(ii):

(i) Transfer to Mundipharma. All of Mundipharma’s rights under Section 2.1 of this Agreement shall continue, and Mundipharma shall require that

(ii) Transition Assistance. Allos shall provide such reasonable assistance, at no cost to Mundipharma, as may be reasonably necessary or useful for Mundipharma to continue Developing the Product throughout the Licensed Territory to the extent Allos is then performing or having performed such activities, including assigning or amending as appropriate, upon request of Mundipharma, any agreements or arrangements with Third Party vendors to Develop the Product. To the extent that any such contract between Allos and a Third Party is not assignable to Mundipharma, Allos shall reasonably cooperate with Mundipharma to arrange to continue to provide such services for a reasonable time after termination; and

(iii) Assumption of PDX License Agreement. Provided that Mundipharma is not in breach of this Agreement at the time the PDX License Agreement terminates, in exercising its rights under Section 12.6(b)(i), Mundipharma will assume all rights and responsibilities of Allos under the PDX License Agreement, including the royalties, milestones and sublicense fees provisions [*], to the extent applicable to the rights granted to Mundipharma under this Agreement (i.e., in respect of the Licensed Territory only).

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[*] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
(i) Transfer to Mundipharma. All of Mundipharma’s rights under Section 2.1 of this Agreement shall continue, and Mundipharma shall require that Allos promptly takes, and Allos hereby agrees to take, such actions as Mundipharma may reasonably request, in order to transfer to Mundipharma or its Affiliates or Sublicensees, free of charge, in respect of the Licensed Territory only, all of the rights, title and interest retained by Allos pursuant to Section 2.1(e), excluding the rights, title and interest of Allos under the PDX License Agreement unless, and only to the extent, the PDX Licensor consents to the assignment of such rights, title and interest (and assumption of the obligations) under the PDX License Agreement in respect of the Licensed Territory. In the event of such an assignment, Allos will, at its expense and at Mundipharma’s request, deliver, execute and/or deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and take or cause to be taken all such actions as may be reasonably necessary to effectuate such transfer (excluding any transfer of the rights, title and interest of Allos under the PDX License Agreement unless, and only to the extent, the PDX Licensor consents to the transfer of such rights, title and interest (and assumption of the obligations) under the PDX License Agreement in respect of the Licensed Territory). Allos will further reconvey and release to Mundipharma all rights and privileges originally granted to Allos by Mundipharma under this Agreement (including those granted under Section 8.9), including those co-exclusive rights, such that all such rights and privileges will vest exclusively with Mundipharma; provided, however, Mundipharma hereby grants to Allos, effective upon termination under Section 12.4(d), a non-exclusive, fully paid, royalty-free limited right and license under any Patent Controlled by Mundipharma that claims the Product or the API or the manufacture or use in the Field of the Product or the API to Develop, make, have made, use, sell, offer for sale, import and otherwise Commercialize the Products throughout the Allos Territory. Mundipharma will, in such circumstances not be required to pay any further milestones required under Section 7.3 of this Agreement, but shall pay to Allos the royalties on all Net Sales of Products in the Licensed Territory set forth in Section 7.4, after deducting (A) royalty payments made to the PDX Licensor (with respect to the same Net Sales) in accordance with Mundipharma’s assumption of the rights and responsibilities of the PDX License.

12.6 Effect of Termination or Expiration (ii) Transition Assistance. Allos shall provide such reasonable assistance, at no cost to Mundipharma, as may be reasonably necessary or useful for Mundipharma to continue Developing the Product throughout the Licensed Territory to the extent Allos is then performing or having performed such activities, including assigning or amending as appropriate, upon request of Mundipharma, any agreements or arrangements with Third Party vendors to Develop the Product. To the extent that any such contract between Allos and a Third Party is not assignable to Mundipharma, Allos shall reasonably cooperate with Mundipharma to arrange to continue to provide such services for a reasonable time after termination; and

(iii) Assumption of PDX License Agreement. Provided that Mundipharma is not in breach of this Agreement on the effective date of termination of this Agreement pursuant to Section 12.4(d), in exercising its rights under Section 12.6(c)(ii), Mundipharma will assume all rights and responsibilities of Allos under the PDX License Agreement, including the royalties, milestones and sublicense fees provisions [*], to the extent applicable to the rights granted to Mundipharma under this Agreement (i.e., in respect of the Licensed Territory only).

12.7 Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: (i) Articles 1 (to the extent defined terms are contained in the following surviving Articles and Sections), 10, 11 (other than Section 11.3) and 13 (other than Section 13.2); (ii) Sections 2.4, 4.10 (for a period of five (5) years after such expiration or termination), 7.2, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.10 (provided that the preceding Sections of Article 7 shall survive only with respect to any payment incurred or accrued prior to such expiration or termination), 8.1, 8.9(i), 9.5, 12.6, 12.7, 14.1, 14.3, 14.4, 14.7, 14.8, 14.9, 14.11 and 14.15; and (iii) solely with respect to Joint Patents, Sections 8.3, 8.4 and 8.5.

ARTICLE 13

DISPUTE RESOLUTION

13.1 Arbitration. In the event of any disputes, controversies or differences which may arise between the Parties (except for disputes arising from the JSC, which shall be handled pursuant to Section 13.2 and only handled pursuant to this Section 13.1 as provided in Section 83
13.2 Referred from JSC. With respect to disputes arising from matters delegated or referred to the JSC pursuant to the terms of this Agreement, either Party may, by written notice to the other Party, have such dispute referred to each Party’s Executive Officers for attempted resolution by good faith negotiations within [*] after such notice is received. If the Executive Officers of the Parties are not able to resolve a dispute within the [*] period described above, then the Executive Officer of Allos or Mundipharma, as the case may be, shall have the unilateral right to cast the deciding vote for the JSC as provided in Section 13.2(a) or 13.2(b). If neither Party has the right to cast the deciding vote for the JSC pursuant to Section 13.2(a) or 13.2(b) (e.g., where Section 13.2(a) or 13.2(b) provides for exceptions to the Executive officer’s right to make the final decision), then either Party may submit the dispute for resolution pursuant to Section 13.1.

(a) Allos Decisions. The Executive Officer of Allos shall have the right to make the final decision with respect to: (i) any decision regarding Development of the Product for the Field in the Allos Territory (except for a decision involving an Additional Study other than an Allos Study) or an Incremental Study being conducted by Allos, except where Mundipharma reasonably believes either that such decision poses a substantial and unwarranted safety risk (a “Safety Reason”) or that such decision is substantially likely to cause a Material Impact; (ii) prior to the Transfer Date, any decision regarding Regulatory Materials with respect to the Product in the Field in the EEA or communicating with Regulatory Authorities in the EEA to obtain or maintain Regulatory Approval in the Field in the EEA, except where Mundipharma reasonably believes either that there is a Safety Reason or that such decision is substantially likely to cause a Material Impact; or (iii) any decision regarding Commercialization of the Product in the Field in the Allos Territory. Nothing in this Section 13.2(a) shall be construed to limit Allos’ (A) ability to carry out day-to-day decisions related to its Development activities as set forth in the Development Plan, (B) compliance with applicable Laws or reporting requirements to Regulatory Authorities, or (C) sole discretion with respect to pricing decisions with respect to the Product in the Allos Territory.

(b) Mundipharma Decisions. The Executive Officer of Mundipharma shall have the right to make the final decision with respect to: (i) any decision regarding Development of the Product for the Field in the Licensed Territory (except for a decision involving an Additional Study or a decision described in Section 13.2(a)(i)) or an Incremental Study being conducted by Mundipharma, except where Allos reasonably believes either that there is a Safety Reason or that such decision is substantially likely to cause a Material Impact; (ii) after the Transfer Date, any decision regarding Regulatory Materials with respect to the Product in the Field in the EEA or communicating with Regulatory Authorities in the EEA to obtain or maintain Regulatory Approval in the Field in the EEA, except where Allos reasonably believes either that there is a Safety Reason or that such decision is substantially likely to cause a Material Impact; or (iii) any decision regarding Commercialization of the Product in the Field in the Licensed Territory. Nothing in this Section 13.2(a) shall be construed to limit Mundipharma’s (A) ability to carry out day-to-day decisions related to its Development activities as set forth in the Development Plan, (B) compliance with applicable Laws or reporting requirements to Regulatory Authorities, or (C) sole discretion with respect to pricing decisions with respect to the Product in the Licensed Territory.

13.3 Equitable Relief. Notwithstanding Sections 13.1 and 13.2, each Party acknowledges that its breach of Article 11 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated by damages in an action at law. By reason thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief from any state or federal court of competent jurisdiction in New York, New York to prevent or curtail any actual or threatened breach of Article 11 that is reasonably likely to cause it irreparable harm. In addition, notwithstanding Sections 13.1 and 13.2, to the fullest extent provided by Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect a Party’s rights or enforce a Party’s obligations under this Agreement pending final resolution of
any claims related thereto pursuant to the dispute resolution procedure set forth in Section 13.1.

13.4 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

13.5 Patent and Trademark Disputes. Notwithstanding Section 13.1, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent or trademark rights outside the U.S. covering the manufacture, use, importation, offer for sale or sale of the Product shall be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

ARTICLE 14

MISCELLANEOUS

14.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, together with the Development Plan, the Supply Agreement, the Consent, the Letter Agreement, the Pharmacovigilance Agreement and the Technical Agreement, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter of this Agreement other than as are set forth in this Agreement, the Development Plan, the Supply Agreement, the Pharmacovigilance Agreement and the Technical Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

14.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall continue for so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties’ obligations under this Agreement in order to mitigate the delays caused by such force majeure.

14.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 14.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) business days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Allos:
Allos Therapeutics, Inc.
11080 Circle Point Road,
Suite 200
Westminster, Colorado 80020
14.4 No Strict Construction; Interpretation; Headings. In the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring either Party by virtue of the authorship of any provisions of this Agreement. The language in this Agreement is to be construed in all cases according to its fair meaning. The definitions of the terms herein apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed
14.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party’s consent to its Affiliates or to a Third Party successor to substantially all of the business of such Party to which this Agreement relates (such Third Party, an “Acquiror”), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. The Allos Technology, in the case of Allos as assignor ortransferor, or the Mundipharma Technology, in the case of Mundipharma as assignor ortransferor, shall exclude any Patents and Information Controlled by any Acquiror (or any Affiliate thereof, excluding a Party hereto as a result of such transaction) except to the extent such Acquiror’s Information or Patents are Controlled by Allos or Mundipharma, as applicable, and are necessary for the Development or Commercialization of Product and utilized in respect of the Product or the API in the Licensed Territory or the Allos Territory, as applicable. Any assignment or transfer of this Agreement must be done together with an assignment or transfer of the Supply Agreement. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.5 shall be null, void and of no legal effect.

14.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

14.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.9 No Waiver. Any delay in enforcing a Party’s rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party’s rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

14.10 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

14.11 English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

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[ Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate. ]
[ 88 ]
14.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail. In addition, facsimile or PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any Party will constitute due execution and delivery of this Agreement.

14.13 Non-Solicitation of Employees. During the Term, neither Party may, directly or indirectly, recruit or solicit any employee of the other Party who became known to the other Party through contact or interactions for the purposes of negotiating or performing this Agreement, without the prior consent of the other Party. For purposes of the foregoing, “recruit” or “solicit” shall not include: (a) circumstances where an employee of a Party initiates contact with the other Party solely on its own with regard to possible employment without being encouraged, suggested, or otherwise induced to make such contact by the other Party; or (b) general solicitations of employment not specifically targeted at employees of a Party, including responses to general advertisements.

14.14 Expenses. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

14.15 Intellectual Property. The Parties acknowledge and agree that the licenses granted by the Parties pursuant to Sections 2.1, 2.2 and 8.9 and all other rights granted under or pursuant to this Agreement are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code (or analogous provisions of the bankruptcy laws of any Governmental Authority), licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code (or analogous foreign provisions), and that this Agreement is an executory contract governed by Section 365(n) of the Bankruptcy Code (or analogous foreign provisions) in the event that a bankruptcy proceeding is commenced involving either Party (as licensor hereunder). Mundipharma, as the licensee of such rights under Section 2.1 and Allos, as the licensee of such rights under Section 2.2, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The foregoing provisions of this Section 14.15 are without prejudice to any rights the Parties may have arising under the Bankruptcy Code or other applicable Laws.

IN WITNESS WHEREOF, the Parties hereto have caused this License, Development and Commercialization Agreement to be executed by their duly authorized officers as of the Effective Date.

MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED

ALLOS THERAPEUTICS, INC.

By:
/s/ Douglas Docherty
Name: Douglas Docherty
Title:

By:
/s/ Paul L. Berns
Name: Paul L. Berns
Title:
General Manager

Title:

President and Chief Executive Officer

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EXHIBIT A

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EXHIBIT B

JOINT PRESS RELEASE

[parties' logos to be inserted]

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Mundipharma International
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5268
mgreer@allos.com
Lara.Dow@mundipharma.co.uk

Allos Therapeutics and Mundipharma Announce Strategic Collaboration for FOLOTYN

— Allos to Receive $50 Million Upfront Payment and Retain Full Commercialization Rights to FOLOTYN in U.S. and Canada; Mundipharma to Co-Develop and Commercialize in the Rest of World —

— Allos to Host Conference Call Today at 4:30 p.m. Eastern Time to Discuss Collaboration and Q1 Financial Results —

WESTMINSTER, Colo., May 10, 2011 — Allos Therapeutics, Inc. (NASDAQ: ALTH) and Mundipharma International Corporation Limited (Mundipharma) today jointly announced that the companies have entered into a strategic collaboration agreement to co-develop FOLOTYN® (pralatrexate injection). Under the agreement, Allos retains full commercialization rights for FOLOTYN in the United States and Canada, with Mundipharma having exclusive rights to commercialize FOLOTYN in all other countries.

FOLOTYN, a folate analogue metabolic inhibitor, is the first and only drug approved in the United States for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), a biologically diverse group of aggressive blood cancers, and is being studied in a number of other hematologic malignancies. Allos is pursuing regulatory approval to market FOLOTYN in the European Union for relapsed or refractory PTCL. Allos’ Marketing Authorisation Application (MAA) was accepted for review by the European Medicines Agency (EMA) in December 2010.
Under the collaboration, Allos will receive an upfront payment of $50 million and potential regulatory and commercial progress- and sales-dependent milestone payments of up to $310.5 million. Allos is also entitled to receive tiered double-digit royalties based on net sales of FOLOTYN within Mundipharma’s licensed territories.

Allos and Mundipharma will jointly fund development costs, initially on a 60:40 basis, which will change to a 50:50 basis if certain pre-defined milestones are achieved, including approval of the MAA currently under review to market FOLOTYN in the European Union. Development funding by Mundipharma will support jointly agreed-upon clinical development activities, including, but not limited to, the planned Phase 3 studies of FOLOTYN in previously undiagnosed PTCL and in combination with bexarotene in relapsed or refractory cutaneous T-cell lymphoma (CTCL). Pursuant to a separate supply agreement with Mundipharma Medical Company, an affiliate of Mundipharma, Allos will supply FOLOTYN for Mundipharma’s clinical and commercial uses.

"Mundipharma is an ideal global partner. They have demonstrated hematology/oncology development, regulatory and commercial capabilities with recent major regulatory and commercial successes in bringing Levact® (bendamustine) to market in Europe for non-Hodgkin lymphoma and other blood cancers, as well as substantial resources to develop and commercialize FOLOTYN,” said Paul L. Berns, president and chief executive officer of Allos Therapeutics, Inc. “We are currently seeking regulatory approval to market FOLOTYN in Europe for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma. Our two companies share a vision for bringing FOLOTYN to patients and believe this collaboration will maximize the development, commercialization and market potential of FOLOTYN in a variety of blood cancers.”

"Mundipharma is delighted to partner with Allos in the development and commercialisation of FOLOTYN and believes that it has worldwide potential to become an important treatment alternative for patients,” commented Åke Wikström, regional director Europe at Mundipharma International Limited. “FOLOTYN represents a very meaningful addition to Mundipharma’s oncology pipeline and reinforces our commitment to improving patients’ quality of life.”

"Lymphoma arising from T-lymphocytes remains a devastating disease and new treatments are urgently needed. FOLOTYN, if approved, may be in many countries the first drug to treat this cancer and this will allow us to work with haematologists to improve the treatment results by developing new and hopefully even more effective drug combinations,” added Dr. Thomas Mehrling, director of European Oncology at Mundipharma International Limited.

About FOLOTYN

FOLOTYN, a folate analogue metabolic inhibitor, was discovered by Sloan-Kettering Institute for Cancer Research, SRI International and Southern Research Institute and developed by Allos Therapeutics. In September 2009, the U.S. Food and Drug Administration (FDA) granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory PTCL. This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated. FOLOTYN has been available to patients in the U.S. since October 2009. An updated analysis of data from PROPEL was published in the March 20, 2011 issue of the Journal of Clinical Oncology.

FDA’s accelerated approval program allows the FDA to approve products for cancer or other life-threatening diseases based on initial positive clinical data. In connection with the accelerated approval, Allos is required to conduct post-approval studies that are intended to verify and describe the clinical benefit of FOLOTYN in patients with T-cell lymphoma. In March 2011, Allos reached agreement with the FDA under its Special Protocol Assessment (SPA) process for the design of Allos’ Phase 3 clinical trial of FOLOTYN in patients with previously undiagnosed PTCL. The study will seek to enroll newly diagnosed patients with PTCL who have achieved a response following initial treatment with a CHOP-based therapy.

Allos is also pursuing regulatory approval to market FOLOTYN in the European Union for relapsed or refractory PTCL. Allos’ MAA was accepted for review by the EMA in December 2010.

Conference Call Information
Allos will host a conference call today, May 10, 2011 at 4:30 p.m. ET, to review its first quarter 2011 financial results and to discuss the details of the collaboration with Mundipharma. Participants can access the call at 1-877-941-1466 (U.S.) or +480-629-9724 (Canada and international). To access the live audio webcast or the subsequent archived recording, visit the “Investors - Presentations and Events” section of the Allos website at www.allos.com. Webcast and telephone replays of the conference call will be available approximately two hours after the completion of the call. Callers can access the replay by dialing 800-406-7325 (domestic) or 303-590-3030 (international). The passcode is 4438057#. The webcast will be recorded and available for replay on Allos’ website until May 24, 2011.

About Peripheral T-Cell Lymphoma

T-cell lymphomas comprise a biologically diverse group of blood cancers that account for approximately 10% to 15% of all cases of non-Hodgkin lymphomas (NHL).(1-3) Allos estimates the current annual incidence of PTCL to be approximately 5,900 patients in the U.S. and approximately 6,000-7,000 patients in the top five European markets. The outcome of patients with PTCL is poor and the majority of patients ultimately have refractory disease to a variety of agents, including multi-agent chemotherapy with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or CHOP-like regimens. The 5-year overall survival rate in these patients is 25% to 40%, depending on sub-type.(4-5)

About Allos Therapeutics

Allos Therapeutics, Inc. (Nasdaq: ALTH) is a biopharmaceutical company committed to the development and commercialization of innovative anti-cancer therapeutics. Allos is currently focused on the development and commercialization of FOLOTYN® (pralatrexate injection), a folate analogue metabolic inhibitor. FOLOTYN is the first and only drug approved in the U.S. for the treatment of patients with relapsed or refractory PTCL. Allos is also developing FOLOTYN in other hematologic malignancies and solid tumors. Allos is headquartered in Westminster, CO. For additional information, please visit www.allos.com.

About Mundipharma

Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies — privately owned companies and joint ventures covering the world’s pharmaceutical markets. These companies worldwide are dedicated to bringing to patients with severe and debilitating diseases the benefits of novel treatment options in fields such haemato-oncology, severe pain and respiratory disease.

For more information www.mundipharma.co.uk

**IMPORTANT SAFETY INFORMATION**

**Warnings and Precautions**

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If >Grade 2 mucositis is observed, omit or modify dose. Patients should be instructed to take folic acid and receive vitamin B12 to potentially reduce treatment-related hematological toxicity and mucositis.

Fatal dermatologic reactions may occur. Dermatologic reactions may be progressive and increase in severity with further treatment. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued.

Tumor lysis syndrome may occur. Monitor patients and treat if needed.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN and pregnant women should be informed of the potential harm to the fetus.
Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment. Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are >Grade 3, omit or modify dose.

Adverse Reactions

The most common adverse reactions were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events are pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea, and thrombocytopenia.

Use in Specific Patient Population

Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

Drug Interactions

Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethoxazole) may result in delayed renal clearance.

Please see FOLOTYN Full Prescribing Information at www.FOLOTYN.com.

Safe Harbor Statement

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding the status and prospects of our commercialization of FOLOTYN for the treatment of patients with relapsed or refractory PTCL; our Marketing Authorisation Application (MAA) for FOLOTYN in Europe; our future product development and regulatory strategies, including our intent to develop or seek regulatory approval for FOLOTYN in additional indications; our strategic collaboration with Mundipharma, including the parties intent to co-develop FOLOTYN in additional indications and Mundipharma’s potential commercialization of FOLOTYN outside the United States and Canada; and other statements that are other than statements of historical facts. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” “continue,” and other similar terminology or the negative of these terms, but their absence does not mean that a particular statement is not forward-looking. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. Important factors that may cause actual results to differ materially from those anticipated include, but are not limited to, the risks and uncertainties associated with the commercialization of FOLOTYN; the ability to expand the approved indications for FOLOTYN; that the design of and data collected from the Company’s pivotal PROPEL trial may not be adequate to demonstrate the safety and efficacy of FOLOTYN for the treatment of patients with relapsed or refractory PTCL; our future product development and commercialization strategies. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and in the Company’s other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this presentation, except as required by law.

Note: The Allos logo and FOLOTYN name are registered trademarks of Allos Therapeutics, Inc.

Sources: Allos Therapeutics, Inc. and Mundipharma International Corporation Limited

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SCHEDULE 1
ALLOS PATENTS
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SCHEDULE 2
CLINICAL TRIAL AGREEMENTS
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