

Dealdoc

Co-promotion agreement for Levadex

Allergan
MAP Pharmaceuticals

Jan 31 2011

Co-promotion agreement for Levadex

Companies: Allergan

MAP Pharmaceuticals

Announcement date: Jan 31 2011

Deal value, US\$m: 20.0 : sum of milestone payments

- Details
- Financials
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Details

Announcement date:
Start date:
Jan 28 2011
Expiry date:
Jan 28 2011
Bigpharma

Industry sectors:

Therapy areas:

Pharmaceutical

Drug delivery Central Nervous System » Headache

> Central Nervous System » Migraine Central Nervous System » Pain

Technology types:

Drug delivery » Transmucosal » Inhaled

Deal components: Co-promotion
Stages of development: Regulatory

Geographic focus: North America » United States

Financials

Deal value, US\$m:20.0 : sum of milestone paymentsMilestones, US\$m:20.0 : for FDA acceptance of NDA filing

Termsheet

Collaboration within the United States for LEVADEX, a self-administered, orally inhaled therapy that has completed Phase III clinical development for the treatment of acute migraine in adults.

Allergan and MAP Pharmaceuticals will co-promote LEVADEX to neurologists and pain specialists in the United States.

Specifically, Allergan will leverage its existing U.S. sales force dedicated to headache specialists using BOTOX for Chronic Migraine, which will be complemented by MAP Pharmaceuticals' field sales force targeting neurologists and pain specialists.

MAP Pharmaceuticals will retain all rights to commercialize LEVADEX outside the United States, as well as to primary care physicians within the United States.

Press Release

2 August 2011

MAP Pharmaceuticals Announces FDA Acceptance for Filing of NDA for LEVADEX®

MOUNTAIN VIEW, Calif., Aug. 2, 2011 /PRNewswire/ -- MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) today announced that its New Drug Application (NDA) for LEVADEX® orally inhaled migraine drug for the potential acute treatment of migraine in adults has been accepted for filing by the U.S. Food and Drug Administration (FDA), with a goal date of March 26, 2012 under the Prescription Drug User Fee Act (PDUFA). In accordance with the Company's collaboration agreement with Allergan, Inc., the FDA's acceptance for filing of the NDA triggers a milestone payment to MAP Pharmaceuticals of \$20 million.

"We are very pleased with the FDA's acceptance of the filing of our LEVADEX NDA submission as it is a significant achievement in the development of LEVADEX," said Timothy S. Nelson, president and chief executive officer of MAP Pharmaceuticals. "This takes us another step forward in our effort to provide the underserved migraine patient population with a potential new treatment option."

The Company's 505(b)(2) NDA submission for LEVADEX includes efficacy and safety data from the pivotal Phase 3 FREEDOM-301 clinical trial and the open-label, safety extension which was designed to evaluate overall safety of LEVADEX over six and 12 months of exposure. In total, more than 475 patients completed six months of treatment and more than 250 patients completed 12 months of treatment. In total, nearly 10,000 migraines were treated. The NDA is also supported by data from a pharmacokinetics (PK) trial evaluating the PK and safety of LEVADEX in smokers and non-smokers, a pharmacodynamics (PD) trial evaluating the acute effects of LEVADEX on pulmonary artery pressure, a thorough QT trial comparing the acute effects of a supra-therapeutic dose of LEVADEX on the cardiac QT interval as measured by electrocardiogram, a safety trial in adult asthmatics and a drug interaction study assessing the impact of CYP3A4 inhibition on LEVADEX pharmacokinetics. There were no drug related serious adverse events reported in any LEVADEX trial.

About LEVADEX®

LEVADEX is an investigational drug for the acute treatment of migraine in adults, for which the Company has submitted a New Drug Application to the U.S. Food and Drug Administration. In the clinical trial, patients administered LEVADEX themselves using the proprietary TEMPO® inhaler. LEVADEX contains a novel formulation of dihydroergotamine (DHE). LEVADEX was evaluated in the efficacy portion of FREEDOM-301, MAP Pharmaceuticals' Phase 3 pivotal trial, which included 395 patients in the LEVADEX arm and 397 patients in the placebo arm. In the Phase 3 trial, patients taking LEVADEX had statistically significant improvement at two hours compared to patients on placebo for all four co-primary endooints:

■Pain relief: 58.7 percent of patients who received LEVADEX compared with 34.5 percent for placebo (p<0.0001); ■Phonophobia free: 52.9 percent of patients who received LEVADEX compared with 33.8 percent for placebo (p<0.0001); ■Photophobia free: 46.6 percent of patients who received LEVADEX compared with 27.2 percent for placebo (p<0.0001); and ■Nausea free: 67.1 percent of patients who received LEVADEX compared with 58.7 percent for placebo (p=0.02).

The most common adverse event reported in the trial was medication aftertaste at six percent versus two percent for placebo. The next most common adverse event was nausea at five percent compared with two percent for placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups.

About Migraine

Migraine is estimated to occur in 18% of women and 6% of men in the United States. Over 30 million people are impacted by the often debilitating symptoms of migraine, including headache pain, nausea, sensitivity to light and sensitivity to sound. While triptans are considered the standard of care for migraine today, there are millions of patients who do not consistently respond to triptans, leaving a large number of patients without adequate treatment for their migraines. According to the National Headache Foundation, most migraines last between four and 24 hours, but some last as long as three days. On average, migraine sufferers experience three migraine attacks monthly, although 25 percent of them experience one or more attacks weekly. The economic burden of migraine remains substantial despite existing treatments, with the direct and indirect costs of migraine in the United States estimated at over \$20 billion annually.

About MAP Pharmaceuticals

MAP Pharmaceuticals is an emerging biopharmaceutical company focused on developing and commercializing new therapies to address undermet patient needs in neurology. The Company is developing LEVADEX, an orally inhaled investigational drug for the acute treatment of migraine. The U.S. Food and Drug Administration has accepted for filing the New Drug Application for LEVADEX for the potential acute treatment of migraine in adults. MAP Pharmaceuticals has entered into a collaboration agreement with Allergan, Inc. to co-promote LEVADEX to neurologists and pain specialists in the U.S. The Company also applies its proprietary drug particle and inhalation technologies to generate new pipeline opportunities by enhancing the therapeutic benefits of proven drugs, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. Additional information about MAP Pharmaceuticals can be found at http://www.mappharma.com.

31 January 2011

Allergan and MAP Pharmaceuticals Announce Collaboration on LEVADEX™ Investigational Therapy for Acute Migraine

Collaboration Intended to Expand Continuum of Care for Migraine Patients and Portfolio Offering to Neurologists and Pain Specialists in United States

IRVINE, Calif. and MOUNTAIN VIEW, Calif., January 31, 2011 - Allergan, Inc. (NYSE: AGN) and MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) today announced a collaboration within the United States for LEVADEX™, a self-administered, orally inhaled therapy that has completed Phase III clinical development for the treatment of acute migraine in adults. MAP Pharmaceuticals currently anticipates submitting its New Drug Application (NDA) for LEVADEX™ with the United States Food and Drug Administration (FDA) in the first half of 2011.

LEVADEX[™] contains a proprietary formulation of dihydroergotamine (DHE), a drug delivered via IV, injection or nasal spray and used in clinical practice today for the treatment of acute migraine. Utilizing MAP Pharmaceuticals' proprietary drug delivery system, the TEMPO® inhaler, the unique formulation can be self-administered by the patient and is absorbed through the lungs. If approved, LEVADEX[™] may offer an easy to use, at-home therapy option for acute migraine sufferers.

Under the terms of the collaboration, following potential FDA approval of LEVADEXTM, Allergan and MAP Pharmaceuticals will co-promote LEVADEXTM to neurologists and pain specialists in the United States. Specifically, Allergan will leverage its existing U.S. sales force dedicated to headache specialists using BOTOX® for Chronic Migraine, which will be complemented by MAP Pharmaceuticals' field sales force targeting neurologists and pain specialists. MAP Pharmaceuticals will retain all rights to commercialize LEVADEXTM outside the United States, as well as to primary care physicians within the United States.

"As a company devoted to the advancement of patient care in specialty areas, including neurosciences, we are pleased to partner with MAP Pharmaceuticals to realize the potential of LEVADEXTM," said David E.I. Pyott, Allergan's Chairman of the Board and Chief Executive Officer. "If approved by the FDA, LEVADEXTM would present a continuum of care to neurologists and pain specialists, LEVADEXTM for acute migraine patients and BOTOX® for Chronic Migraine patients."

"Allergan is an established leader in neurosciences with a proven track record of scientific innovation, securing FDA approvals and commercializing products to neurologists and pain specialists in the United States," said Timothy S. Nelson, MAP Pharmaceuticals' President and Chief Executive Officer. "Their commitment to neurosciences and their understanding of the needs of our target physicians for LEVADEXTM have been demonstrated through the ongoing evolution of BOTOX®, including its recent FDA approval for Chronic Migraine patients. They are the ideal partner to help us best serve this specialty segment and to provide the resources needed to successfully launch and commercialize LEVADEXTM upon potential FDA approval."

As part of the collaboration, MAP Pharmaceuticals will be responsible for the manufacturing and distribution of LEVADEXTM in the United States, and for recording product revenue. Leveraging Allergan's expertise in pursuing innovation and securing market authorization, the companies have also agreed, following potential approval of LEVADEXTM for the treatment of acute migraine in adults, to jointly develop LEVADEXTM for additional indications, including adolescent migraine and one additional headache disorder. The companies will work through joint committees to manage all development and commercial activities. MAP Pharmaceuticals will be responsible for obtaining NDA approval, and will retain ownership of the NDA.

MAP Pharmaceuticals will receive a \$60 million up-front payment from Allergan and up to \$97 million in additional payments upon meeting certain regulatory milestones associated with the initial indication. If LEVADEX™ receives FDA approval, the companies will equally share profits from sales of LEVADEX™ generated from its commercialization to neurologists and pain specialists in the United States.

MAP Pharmaceuticals Conference Call / Webcast Details

To participate in the live call today, on Monday, January 31, at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time), please dial 877-280-7473 for domestic callers and 707-287-9370 for international callers. Individuals interested in listening to the call via webcast may do so by visiting the Investor Relations page of http://www.mappharma.com.

About LEVADEX™ Investigational Acute Migraine Therapy

LEVADEX[™] is an investigational therapy for acute migraine that has completed Phase III clinical development. In the clinical trial, patients administered LEVADEX[™] themselves using the proprietary TEMPO® inhaler. LEVADEX[™] contains a novel formulation of dihydroergotamine (DHE). LEVADEX[™] was evaluated in the efficacy portion of FREEDOM-301, MAP Pharmaceuticals' Phase III pivotal trial, which included 395 patients in the LEVADEX[™] arm and 397 patients in the placebo arm. In the Phase III trial, patients taking LEVADEX[™] therapy had statistically significant improvement at two hours compared to patients on placebo for all four co-primary endpoints:

- ■Pain relief: 58.7 percent of patients who received LEVADEX[™] compared with 34.5 percent for placebo (p<0.0001);
- ■Phonophobia free: 52.9 percent of patients who received LEVADEX[™] compared with 33.8 percent for placebo (p<0.0001);
- ■Photophobia free: 46.6 percent of patients who received LEVADEX[™] compared with 27.2 percent for placebo (p<0.0001); and
- ■Nausea free: 67.1 percent of patients who received LEVADEX[™] compared with 58.7 percent for placebo (p=0.02).

The most common adverse event reported was medication aftertaste at six percent versus two percent for placebo. The next most common adverse event was nausea at five percent compared with two percent for placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups.

About Migraine

Common symptoms of migraine include recurrent headaches, nausea, vomiting, photophobia (sensitivity to light) and phonophobia (sensitivity to sound). According to the National Headache Foundation, most migraines last between four and 24 hours, but some last as long as three days1. On average, migraine sufferers experience 1.5 migraine attacks monthly, although 25 percent of them experience one or more attacks weekly2. The economic burden of migraine remains substantial despite existing treatments, with the direct and indirect costs of migraine in the United States estimated at over \$20 billion annually.3,4

About BOTOX® (onabotulinumtoxinA) Important Information

Indications BOTOX® is a prescription medicine that is injected into muscles and used:

- ■to treat headaches in adults with Chronic Migraine (15 or more days with headaches lasting four hours a day or longer) in people 18 years or older.
- ■to treat increased muscle stiffness in elbow, wrist, and finger muscles with upper limb spasticity in people 18 years and older.
- ■to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older.
- ■to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX® is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough in people 18 years and older.

It is not known whether BOTOX® is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

It is not known whether BOTOX® is safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- ■Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- ■Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® (onabotulinumtoxinA) has been used at the recommended dose to treat Chronic Migraine, severe underarm sweating, blepharospasm, or strabismus.

Do not take BOTOX® if you: are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as Myobloc® or Dysport™; have a skin infection at the planned injection site.

For more information refer to the Medication Guide or talk with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information on BOTOX® (onabotulinumtoxinA) please see BOTOX® full Product Information, including Medication Guide. Full Product Information, including Medication Guide has been provided to your doctor

About MAP Pharmaceuticals

MAP Pharmaceuticals is an emerging biopharmaceutical company focused on developing and commercializing new therapies to address undermet patient needs in neurology. The Company is developing LEVADEXTM orally inhaled therapy for the potential treatment of migraine and has reported positive results from the efficacy portion of its Phase 3 trial of LEVADEXTM. In addition, MAP Pharmaceuticals generates new pipeline opportunities by applying its proprietary drug particle and inhalation technologies to enhance the therapeutic benefits of proven drugs, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history. Additional information about MAP Pharmaceuticals can be found at http://www.mappharma.com

About Allergan, Inc.

Allergan is a multi-specialty health care company established 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life's potential. Today, we have more than 9,000 highly dedicated and

talented employees, global marketing and sales capabilities with a presence in more than 100 countries, a rich and ever-evolving portfolio of pharmaceuticals, biologics and medical devices, and state-of-the-art resources in R&D, manufacturing and safety surveillance that help millions of patients see more clearly, move more freely and express themselves more fully. From our beginnings as an eye care company to our focus today on several medical specialties, including ophthalmology, neurosciences, obesity, urologics, medical aesthetics and dermatology, Allergan is proud to celebrate 60 years of medical advances and proud to support the patients and physicians who rely on our products and the employees and communities in which we live and work.

Filing Data

Not available.

Contract

CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this "Agreement") is made and entered into effective as of January 28, 2011, by and between MAP Pharmaceuticals, Inc., a Delaware corporation having an address at 2400 Bayshore Parkway, Suite 200, Mountain View, California 94043 ("MAP"), and ALLERGAN USA, Inc., a Delaware corporation having an address at 2525 Dupont Drive, Irvine, California 92612 ("ALLERGAN"). MAP and ALLERGAN are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, ALLERGAN and MAP have entered into a Collaboration Agreement dated January 28, 2011 (the "Collaboration Agreement");

WHEREAS, the Collaboration Agreement grants ALLERGAN certain co-exclusive rights to Commercialize Product to Physician Targets for use in the Field in the Territory; and

WHEREAS, the Parties desire for MAP and ALLERGAN to Commercialize Product to Physician Targets for use in the Field in the Co-Promotion Territory pursuant to the terms and conditions of this Agreement and the Collaboration Agreement.

NOW, THEREFORE, in consideration of the foregoing promises and the mutual representations, warranties, covenants and agreements contained herein and in the Collaboration Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

- 1.1 Definitions. All capitalized terms not otherwise defined herein shall have the meaning given to them in the Collaboration Agreement. The following terms shall have the meanings set forth next to them when used in this Agreement:
- (a) "Co-Promotion Territory" means the United States of America.
- (b) "DDMAC" means the Division of Drug Marketing, Advertising and Communication of the FDA.
- (c) "Deficiency" means, for any Deficient Quarter, with respect to the applicable Party, the percentage calculated using the following formula: ((A-B)/A), where A is the minimum number of PDEs assigned to such Party under the Collaboration Agreement or any then-current, mutually agreed upon Commercialization Plan for such Calendar Quarter, and B is the number of PDEs actually delivered by the Sales Force of such Party during such Calendar Quarter.

- (d) "Deficient Quarter" means, with respect to a Party, the Calendar Quarter during which the Sales Force of such Party delivered fewer PDEs than the minimum number of PDEs assigned to such Party for such Calendar Quarter under the Collaboration Agreement or any then-current, mutually agreed upon Commercialization Plan.
- (e) "FD&C Act" means the United States Food, Drug and Cosmetic Act, as amended from time to time (21 U.S.C. Section 301 et seq.), together with any rules and regulations promulgated thereunder.
- (f) "Initial Three-Year Period" means the three (3) year period immediately following First Commercial Sale.
- (g) "Labeling" means (i) the FDA full prescribing information for Product in the Field, including any required patient information, and (ii) all labels and other written, printed or graphic matter upon any container, wrapper or any package insert or outsert utilized with or for Product in the Field.

- (h) "PDMA" means the Prescription Drug Marketing Act of 1987, as amended from time to time, together with any rules and regulations promulgated thereunder.
- (i) "Promotion Related Activities" means lunches, snacks, dinners, entertainment, or medically related gifts for health care professionals with prescribing authority used to promote Product to such persons. For purposes of this Agreement, Promotion Related Activities expressly excludes conference or convention participation, continuing medical education programs, grants, paid speaker programs, symposiums and entertainment.
- (j) "Samples" means quantities of Product given to authorized medical professionals for no or minimal consideration as part of the marketing, advertising and promotion of Product.
- (k) "Training Materials" means the items the JCC develops or approves after the Effective Date to train persons to promote Product in the Co-Promotion Territory.

ARTICLE 2

CO-PROMOTION RIGHTS AND OBLIGATIONS

- 2.1 Co-Promotion Right. As set forth herein and in the Collaboration Agreement, the Parties have the right and obligation to jointly Commercialize Product to Physician Targets for use in the Field in the Co-Promotion Territory.
- 2.2 Performance. The Parties, through the JCC, will be responsible for the day-to-day Commercialization activities for Product to Physician Targets for use in the Field in the Co-Promotion Territory. Subject to the terms of this Agreement and the Collaboration Agreement, the Parties shall have the right and responsibility to field personnel and take actions related to Commercializing Product to Physician Targets for use in the Field in the Co-Promotion Territory during the Term, including the following:

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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (a) Each Party shall perform its respective obligations under this Agreement, the Collaboration Agreement and the Commercialization Plan.
- (b) Following receipt of Regulatory Approval of the Initial Indication in the Co-Promotion Territory, each Party shall use its Commercially Reasonable Efforts to Commercialize Product to Physician Targets in the Field in the Co-Promotion Territory and shall fulfill its obligations under this Agreement and the Collaboration Agreement. The Parties shall deploy each of their respective Sales Forces in an effort to Commercialize Product to Physician Targets in the Field in the Co-Promotion Territory in accordance with the Commercialization Plan in effect from time to time, the directions of the JCC, and the terms of this Agreement and the Collaboration Agreement.
- (c) Exhibit A to this Agreement sets forth the calculations of the following items which shall be incorporated into the initial Commercialization Plan: minimum Calendar Quarter PDE requirements; PDE Rate; Calendar Quarter PDE expenses at PDE minimums; and Calendar Quarter PDE caps. Upon mutual written agreement of the Parties, the items and calculations may be adjusted for purposes of preparing any new Commercialization Plans. In no event shall a Party be entitled to include as a Shared Expense or in the calculation of Net Sales, or otherwise be entitled to reimbursement for, any PDE Cost amount in excess of the Calendar Quarter PDE caps set forth on Exhibit A (as may be amended from time to time). Upon the adjustment of the PDE ratios as provided in the definition of "PDE", the Parties shall mutually agree upon appropriate and equitable adjustments in the calculations of the items on Exhibit A to reflect such changes.
- (d) In implementing the obligations contained in this Agreement, each Party shall [***] (which shall not be inconsistent with the Commercialization Plan, this Agreement and the Collaboration Agreement, and provided that neither Party will utilize any Promotional Materials not approved by the JCC) in which it promotes and Details (including any expenditure of funds in connection therewith) Product in the Co-Promotion Territory.
- (e) Neither Party shall distribute or have distributed any information that bears the name or logo of the other Party without the prior approval of the other through the JSC or the JCC, which approval shall not be unreasonably withheld, conditioned or delayed.
- 2.3 Joint Commercialization Activities. Subject to the requirements set forth in the Collaboration Agreement and the then-current Commercialization Plan, each Party shall be responsible for performing Commercialization activities as described below:
- (a) Commercialization Plan. In addition to those items set forth in Article 6 of the Collaboration Agreement and subject to the minimum obligations set forth herein and in the Collaboration Agreement, the Commercialization Plan shall specify with respect to Commercialization to Physician Targets for use in the Field in the Co-Promotion Territory:
- i. Promotional Materials to be used;

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ii. Subject to the minimum requirements set forth herein and in the Collaboration Agreement, the number of PDEs that each Party and each respective Sales Force representative must perform in each Calendar Year;
iii. Detailing strategy and obligations of the Parties on a Calendar Year basis, including (a) the "call plan" size (i.e., the number of Physician Targets to be called on by each Sales Force representative); (b) identification and prioritization of Physician Targets by deciles; (c) reach and frequency expectations for the Physician Targets in each Calendar Period; and (d) the number and position of PDEs for Product to be performed in each Calendar Year;
iv. the reporting obligations of the Parties and their Sales Force representatives with respect to the performance of their Commercialization activities under this Agreement, including the recording of Detailing activity by Sales Force representatives, the review by Sales Force representatives of the activities of their counterparts on the other Party's Sales Force, and the hardware, software and other information technology to be used therefor;
v. sales forecasts for Product on a Calendar Quarter basis (or more frequently if so determined by the Parties);
vi. compensation packages for sales representatives including incentive compensation;
vii. Product pricing strategy and managed care and reimbursement plans;
viii. budget for such activities; and
ix. such other plans relating to Commercialization as the Parties deems necessary or appropriate.
(b) Sales Forces. The Commercialization Plan will set forth in reasonable detail all material matters related to Sales Force activities with respect to Product to Physician Targets in the Field in the Co-Promotion Territory. Subject to and in accordance with the provisions of this Agreement, the Collaboration Agreement and the Commercialization Plan, each Party shall:
i. be solely responsible for recruiting, hiring, managing, maintaining, disciplining, firing, compensating (including paying for all benefits, wages, special incentives, workers' compensation, and employment taxes) and otherwise controlling its respective Sales Force and for paying for any and all costs associated with its Sales Force's efforts;
ii. provide the day-to-day management of its Sales Force, including, without limitation, furnishing administrative support, financial resources, equipment, and supplies, monitoring detail reporting and Sample accounting, and assuring the Sales
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[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.
Force's understanding and compliance with this Agreement, the Collaboration Agreement, the Commercialization Plan and Applicable Laws;
iii. utilize its Commercially Reasonable Efforts to deploy its Sales Force to Commercialize to Physician Targets for use in the Field in the Co-Promotion Territory during the Term, after Regulatory Approval has been received for the Initial Indication for Product in the Field in the Co-Promotion Territory; and
iv. for the avoidance of doubt, at all times be obligated to meet such Party's minimum obligations as set forth in the Collaboration Agreement.
(c) Training. The Parties shall establish procedures for jointly training sales personnel and for preparation of Training Materials related to

(c) Training. The Parties shall establish procedures for jointly training sales personnel and for preparation of Training Materials related to Commercialization of Product to Target Physicians in the Field in the Co-Promotion Territory. In addition, the Parties shall be responsible for preparing all sales Training Materials with regard to Product to Physician Targets for use in the Field in the Co-Promotion Territory, such training to include a reasonable proficiency examination. Both Parties agree to utilize only sales Training Materials that have been approved by each Party's respective legal and regulatory departments. Training shall include a home study period and an initial classroom-setting training program, which shall include medical and technical information about use of Product in the Field in the Co-Promotion Territory. The Parties shall direct which personnel shall receive training on the use of Product in the Field and which Party shall perform the training. Only personnel who have passed the proficiency examination with a minimum [***] proficiency are qualified to Commercialize Product to Physician Targets for use in the Field in the Co-Promotion Territory. The Parties shall share training costs as set forth in the Collaboration Agreement. The Parties acknowledge that their respective Sales Forces must be trained, qualified and ready to launch, Commercialize and Detail Product to Physician Targets for use in the Field in the Co-Promotion Territory on the date of launch as specified in the then-current Commercialization Plan; provided that such date shall be no later than the date specified for such Party in the Collaboration Plan.

- (d) Sales Force Meetings. The Parties will work together to coordinate the timing and location of Sales Force meetings regarding Product. The Parties shall have at least one (1) joint national sales meeting per Calendar Year. If such national sales meeting involves products other than Product, ALLERGAN shall not have the right to participate in those sections that specifically relate to the other MAP products, and MAP shall not have the right to participate in those sections that specifically relate to the other ALLERGAN products. The Parties shall share Sales Force meeting costs as set forth in the Collaboration Agreement.
- (e) Sales Territories. The sales territories, sales districts, and sales regions for the [***] sales territories, sales districts and sales regions for [***]. If [***] its territories, sales districts or sales regions [***] shall in good faith consider the [***], but shall not be obligated to [***] for each state, territory, possession and protectorate within the [***].
- (f) Samples. The Parties shall determine the appropriate level of and process for Product sampling. MAP shall supply all Samples, the costs and expenses of which are included in Shared Expenses, subject to the provisions of the Collaboration Agreement. Each

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Party will transport, store, handle and distribute all Samples, as may be determined by the Parties, in compliance with Applicable Laws and with the procedures established by the JCC.

- (g) Compensation.
- i. Each Party shall use its Commercially Reasonable Efforts to ensure that variable pay components of its compensation structure, including but not limited to incentives ("Incentive Compensation"), for its Sales Force with responsibility for Commercializing Product are consistent with practices used for other similar products. To facilitate the determination of Product incentives, the Parties will work together to coordinate annual sales plans.
- ii. In furtherance of and without limiting the foregoing, MAP shall allocate [***] of Sales Force Incentive Compensation to Product for the shorter of [***], and [***].
- iii. Notwithstanding anything contained in this Agreement or in the Collaboration Agreement, ALLERGAN will allocate [***] of ALLERGAN Sales Force Incentive Compensation to Product [***].
- (h) Promotion of Other Products. Subject to the provisions of this Agreement, while this Agreement is in effect, each Party has the right to have its Sales Force Detail products other than Product in any detail positions not reserved by the Parties for Product. [***].
- (i) Product Complaints. The Parties will establish appropriate procedures for handling and reporting of Product complaints.
- (j) Medical Inquiries. The Parties will establish appropriate procedures for dealing with medical inquiries related to Product.
- (k) Managed Care. The Parties shall coordinate activities with respect to Product across managed care market segments in the Field in the Co-Promotion Territory including: (i) contract strategy, (ii) contract creation; (iii) government reporting, rebate processing, calculations and pricing schedules; (iv) contract compliance, monitoring and audits; (v) contract administration and claims processing; and (vi) all other matters related to managed care. [***] to Detail or otherwise Commercialize Product to any Physician Targets or to any contracting agents, medical directors, formulary decision makers, benefit managers, or administrators (even if such persons are health care professionals legally authorized to prescribe Product) of a managed care organization (e.g., health maintenance organization, prescription benefits manager, insurance company, or similar entity), government-funded insurance or medical program, or employer. All Product Commercialization and contracting activities with managed care entities will be conducted by the designated Party.
- (I) Conflicts Between Agreements. For the avoidance of doubt and notwithstanding any provision contained herein, in the Collaboration Agreement, or in the then-applicable Commercialization Plan, the minimum obligations set forth in any Commercialization

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Plan shall equal or exceed the minimum obligations of the Parties, respectively, set forth in this Agreement and the Collaboration Agreement, unless expressly agreed upon in a written document signed by both Parties. In the event of any discrepancy between this Agreement and the Collaboration Agreement, on the one hand, and any Commercialization Plan, on the other, the terms and conditions of this Agreement and the Collaboration Agreement (taking into account the provisions of Section 7.1 hereof) shall control.

- 2.4 Consequences of Failure to Perform Required PDEs.
- (a) Detail Deficiencies. For any Deficient Quarter or Deficient Quarters in which a Party's Sales Force delivers fewer than [***] of the minimum PDEs assigned to it under the Collaboration Agreement or in the then-current, mutually agreed upon Commercialization Plan for such Calendar Quarter or Calendar Quarters:
- i. If a Party fails to perform at least [***] of the aggregate minimum required PDEs for Product for the then-current Calendar Quarter, but performs at least [***] of such required PDEs, then the Party shall be entitled to carry such PDE Deficiencies forward to the following Calendar Quarter. Deficiencies that are carried forward to the next Calendar Quarter shall be included in the calculation of the PDEs assigned in the successive Calendar Quarters, until satisfied in full.
- ii. If a Party fails to perform at least [***] of the aggregate minimum required PDEs for Product for the then-current Calendar Quarter, then the other Party shall be entitled to a credit equal to the difference between [***] of the minimum required PDEs and the actual PDEs performed, such number of PDEs then multiplied by [***], which shall be credited to the other Party's share of Distributable Profit or Distributable Loss.
- (b) If either Party is more than [***] Deficient in [***], then such Party will be deemed to have not used Commercially Reasonable Efforts in Commercializing Product and the other Party shall have the right to terminate this Agreement and the Collaboration Agreement upon written notice; provided, that any such termination shall not affect the right of the Party terminating the Agreement from pursuing any and all other remedies that may be available to it.
- (c) Each Party shall be entitled to audit the records of the other Party (as well as the records of the other Party's subcontractors) to verify such other Party's delivery of PDEs under this Agreement pursuant to the audit provisions of the Collaboration Agreement.
- 2.5 Promotional Materials.
- (a) The Parties shall establish a tracking system for Promotional Materials to ensure that all such Promotional Materials are accurately tracked and submitted to the FDA. MAP will file all Promotional Materials with the FDA if, and as required, by FDA regulations. According to the agreed Commercialization Plan the JCC shall oversee the development and production of all written, printed, electronic and graphic promotional materials including all product labels and inserts to be used by the Parties. Both Parties agree to utilize only

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Promotional Materials that have been approved by each Party's respective legal and regulatory departments.

- (b) The Parties shall not create, develop or distribute any sales, promotional content or other similar materials (including Labeling) relating to Product for Commercialization to Target Physicians in the Field in the Co-Promotion Territory except as set forth in this Section. All oral communications that the Parties or its Sales Force has with Third Parties relating to Product shall conform to the pre-approved talking points (which shall be the same for the Sales Force of both Parties) as recommended by the JCC and shall be subject to review by the JSC.
- 2.6 Cessation of Use of Materials. If the Party responsible for Training Material, Promotional Material or Samples informs the JCC in writing that a Training Material, Promotional Material, or Sample may no longer be used or distributed, each Party agrees that it will not allow its Sales Force to use or distribute such Training Material, Promotional Material, or Sample after the no-use date identified by the responsible Party in its notice.

ARTICLE 3

SALES AND EXPENSES

- 3.1 Sales and Distribution. Through the JCC, the Parties will establish the terms and conditions with respect to the Commercialization of Product to Physician Targets for use in the Field in the Co-Promotion Territory, including, without limitation, [***].
- 3.2 Sales Budget. As set forth in the Collaboration Agreement, Sales Force members shall be reimbursed at an FTE Rate equal to [***] per FTE, which amount may be subject to change from time to time during the Term upon mutual agreement of the Parties.

ARTICLE 4

OPERATING PROCEDURES

- 4.1 Exchange of Information.
- (a) Exchange of Information Generally. Each Party shall provide the other Party with such information as the other Party may reasonably request during the Term in order to support the requesting Party's Sales Force's Commercialization and Detailing of Product to Physician Targets for use

in the Field in the Co-Promotion Territory. During the Term and subject to the provisions of this Agreement, each Party will provide the other with all information that the disclosing Party reasonably deems significant and relevant to the Commercialization and Detailing of Product to Physician Targets for use in the Field in the Co-Promotion Territory within a reasonable time after such information becomes known to the Party; provided, however, that such information is not received from an independent Third Party under a confidentiality obligation. The JCC shall establish reasonable procedures for monitoring of Sales Force activities to ensure that each Party is complying with its obligations under this Agreement.

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- (b) Electronic Reporting. The Parties shall utilize an electronic sales force automation system for data collection and data management consistent with industry standard practices to produce reports and analyses of their respective Sales Force's activities and Product performance with Physician Targets in the Field in the Co-Promotion Territory. The Parties shall provide an electronic call reporting system to each member of their respective Sales Force. The deployed system shall be in compliance with Applicable Laws. Each Sales Force member shall produce detailed electronic notes following each Detail. Each Sales Force member shall be responsible for Detail planning and Detail routing, using sales data to plan, monitor and measure territory performance, as well as reporting useful marketing information obtained for Product in the Co-Promotion Territory, [***]. Within thirty (30) days after the end of each calendar month, the Parties will share reports summarizing Sales Force activity collected from such electronic call reporting system(s) in the prior calendar month. Specific reportable information shall at a minimum include: (i) total number of PDEs reported for each Sales Force member, by month, by Calendar Quarter and year-to-date; (ii) aggregate PDEs by month, by Calendar Quarter and year-to-date aggregate PDEs versus the monthly, by Calendar Quarter and year-to-date goal as specified in the then-current Commercialization Plan. Such information shall be reported in a Microsoft Excel electronic file format or such other format as reasonably agreed by the Parties.
- (c) Other Reporting. The Parties shall report to each other all information necessary to permit each Party to make timely reports as required by any governmental regulatory agency regarding Product. Each Party shall promptly communicate to the other Party all comments, statements, requests and inquiries of the medical profession or any other Third Parties relating to Product in the Field in the Co-Promotion Territory that are out of the ordinary, or not covered by the Labeling, of which such Party becomes aware. All responses to such inquiries of the medical profession or such other Third Parties within the Co-Promotion Territory shall be handled as designated by the JCC. The Parties shall refer all medical inquiries concerning Product in the Field and all quality complaints within the Co-Promotion Territory to a designated address and/or telephone number agreed upon by the Parties.

4.2 Compliance.

(a) The Parties shall conform their practices and procedures relating to Commercializing and Detailing of Product in the Field in the Co-Promotion Territory to policies and procedures, as determined by the JCC from time to time (the "Policies"), but in no event less than the requirements of all applicable Laws and guidelines, including the FD&C Act, the PDMA, the requirements of DDMAC, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code of Pharmaceutical Marketing Practices (the "PhRMA Code") and the American Medical Association ("AMA") Guidelines on Gifts to Physicians from Industry (the "AMA Guidelines"), as the same may be amended from time to time. Each Party shall promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports with respect to Commercializing, Detailing and/or promotion of Product in the Field in the Co-Promotion Territory submitted to or received from the U.S. Department of Health and

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Human Services or its components (including the FDA and the Office of the Inspector General), PhRMA or the AMA relating to such Laws and quidelines.

- (b) The Parties shall in all material respects conform their practices and procedures relating to educating the medical community in the Co-Promotion Territory with respect to Product in the Field in the Co-Promotion Territory to the Policies, the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support of Continuing Medical Education (the "ACCME Standards") and any applicable FDA regulations or guidelines, as the same may be amended from time to time. Each Party shall promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports submitted to or received from the ACCME with respect to Product in the Field in the Co-Promotion Territory relating to the ACCME Standards or such FDA regulations or guidelines.
- (c) The Parties shall provide each member of its Sales Force (prior to performance of services hereunder), with a copy of the then-current code of ethics of the respective Party. The Parties shall ensure that each member of its Sales Force acknowledges in writing receipt of, and will

comply with, the then-current code of ethics in performing services under this Agreement and the Collaboration Agreement.

- (d) In connection with Commercialization and Detailing of Product hereunder, neither Party nor any member(s) of their respective Sales Forces shall knowingly make any false or misleading statement, or make any representation or warranty, oral or written, to Third Parties, concerning Product that is inconsistent with, or contrary to, the Labeling or Promotional Materials or that is disparaging to Product, the other Party, or any of other Party's Affiliates, officers, directors or employees.
- 4.3 Independent Contractors. For all purposes, and notwithstanding any other provisions of this Agreement to the contrary, the legal relationship under this Agreement of the Parties shall be that of independent contractors. It is further understood and agreed that the Parties are engaged in the operation of their own respective businesses, and neither Party is to be considered the agent of the other Party for any purpose whatsoever. Neither Party will have any authority to enter into any contracts or assume any obligations for the other Party nor make any warranties or representations on behalf of that other Party.

ARTICLE 5

REPRESENTATIONS, WARRANTIES AND COVENANTS

- 5.1 The Parties' Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party that:
- (a) it is not debarred under the Generic Drug Enforcement Act of 1992 (the "GDE Act") and is in compliance with the provisions of the GDE Act;
- (b) while this Agreement is in effect, it will comply with the GDE Act, will not become debarred under the GDE Act, and will not use in connection with this Agreement the services of any person or entity debarred under the GDE Act;

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- (c) upon request by the other Party, a Party will certify its compliance with the GDE Act and this Section in writing to such other Party;
- (d) no employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without the other Party's authorized written approval.
- 5.2 MAP Representations, Warranties, and Covenants. MAP represents, warrants and covenants that:
- (a) MAP has or shall have at the time required the requisite personnel, facilities, equipment, expertise, experience and skill to perform its obligations hereunder and to render the services contemplated hereby;
- (b) MAP and its Sales Force shall perform the services in a professional, timely, competent and efficient manner, and it and its Sales Force shall abide by all Laws that apply to its and their performance;
- (c) any negligent or wrongful act or omission on the part of MAP's Sales Force (both individually and as a group) shall be deemed to be negligent or wrongful acts or omissions of MAP. MAP shall notify ALLERGAN in writing as promptly as practicable of any alleged negligent or wrongful acts or omissions on the part of MAP's Sales Force, and of any allegations of negligent or wrongful acts or omissions made against ALLERGAN's Sales Force; and
- (d) at the time MAP delivers Samples to ALLERGAN, MAP represents and warrants to ALLERGAN that such Samples:
- i. comply in all material respects with the Product Specifications;
- ii. comply in all material respects with the FD&C Act;
- iii. are not products that have been adulterated or misbranded within the meaning set forth in FD&C Act and any state or local law or regulation substantially similar to FD&C Act;
- iv. are products that may be introduced into interstate commerce; and
- v. have been manufactured, packaged, stored, and shipped in conformity with all applicable cGMP.
- 5.3 ALLERGAN Warranties and Covenants. ALLERGAN warrants and covenants that:

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- (a) ALLERGAN has the requisite personnel, facilities, equipment, expertise, experience and skill to perform its obligations hereunder and to render the services contemplated hereby;
- (b) ALLERGAN and its Sales Force shall perform such services in a professional, timely, competent and efficient manner, and it and its Sales Force shall abide by all Applicable Laws that apply to its and their performance; and
- (c) any negligent or wrongful act or omission on the part of ALLERGAN's Sales Force (both individually and as a group) shall be deemed to be negligent or wrongful acts or omissions of ALLERGAN. ALLERGAN shall notify MAP in writing as promptly as practicable of any alleged negligent or wrongful acts or omissions on the part of ALLERGAN's Sales Force, and of any allegations of negligent or wrongful acts or omissions made against MAP's Sales Force.
- 5.4 Notice of Breach. If, at any time, a Party is aware that it has materially breached a representation, warranty or covenant under this Agreement, the breaching Party will promptly notify the other Party of such material breach.
- 5.5 Performance by Affiliates. The Parties recognize that a Party may perform some or all of its obligations under this Agreement through its Affiliates.
- 5.6 DISCLAIMER OF ALL OTHER WARRANTIES. THE WARRANTIES SET FORTH IN THIS AGREEMENT AND THE COLLABORATION AGREEMENT ARE THE PARTIES' ONLY WARRANTIES WITH RESPECT HERETO AND ARE MADE EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED, INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR OTHERWISE.
- 5.7 LIMITATION OF LIABILITY. WITHOUT LIMITING THE PARTIES' INDEMNIFICATION OBLIGATIONS UNDER THE COLLABORATION AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

ARTICLE 6

TERM AND TERMINATION

- 6.1 Term. The term of this Agreement shall commence on the Effective Date and continue until the earlier of (a) termination of the Collaboration Agreement or (b) the date on which this Agreement is terminated pursuant to the provisions herein (the "Term").
- 6.2 Effect of Termination or Expiration. Termination or expiration of this Agreement in whole or in part shall not relieve the Parties of any amounts owing between them

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at the date termination or expiration. Upon termination or expiration of this Agreement, ALLERGAN shall, at its sole expense and within thirty (30) days of such termination or expiration, return to MAP all Promotional Materials and any Samples of Product then in the possession of ALLERGAN and any of its Sales Force; provided, however, that ALLERGAN shall be entitled to retain one (1) copy of such Promotional Materials, (a) to the extent reasonably required to allow ALLERGAN to carry out any remaining obligations under this Agreement or the Collaboration Agreement or to exercise any of its rights that expressly survive termination or expiration of this Agreement or the Collaboration Agreement, and (b) for legal archival purposes and/or as may be required by Applicable Law. The following provisions shall survive any termination or expiration of this Agreement: Articles 1 and 7 and Sections 2.3(l), 5.6, 5.7 and 6.2.

ARTICLE 7

GENERAL PROVISIONS

7.1 Incorporation of Terms from the Collaboration Agreement. This Agreement forms an integral part of the Collaboration Agreement, and is incorporated into the Collaboration Agreement. As a part of the Collaboration Agreement is subject to all terms and conditions of the Collaboration Agreement. Without limiting the generality of the foregoing, Article 6 and Article 18 of the Collaboration Agreement each apply to this Agreement as if stated herein. In the event of any contradictions or inconsistencies between the terms of this Agreement and those of the

Collaboration Agreement, the terms of the Collaboration Agreement shall govern.

7.2 Addition of Canada to Territory. The Parties acknowledge and agree that if Canada becomes part of the Territory in accordance with the terms of the Collaboration Agreement, the Parties or their respective Affiliates will enter into a separate co-promotion agreement with respect to Canada, or amend this Agreement to include terms that are specific to Canada and the Parties' (or their respective Affiliates') obligations with respect to promotion of Product in Canada, in accordance with the Collaboration Agreement.

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In Witness Whereof, the Parties have as of the date first set forth above duly executed this Agreement.

ALLERGAN USA, INC. MAP PHARMACEUTICALS, INC.

By: /s/ David E.I. Pyott

By: /s/ Timothy S. Nelson

Name: David E.I. Pyott

Name: Timothy S. Nelson

Title: Chief Executive Officer

Title: President and CEO

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EXHIBIT A

Calculations for Certain Items in Initial Commercialization Plan

Allergan MAP

Minimum Calendar Quarter PDE Requirements

[***] [***]

PDE Rates

[***] [***]

Calendar Quarter PDE Expense at PDE Minimum

[***] [***]

Calendar Quarter PDE Expense Cap

[***] [***]

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