Current Agreements

Dealdoc

Asset purchase agreement for Abstral (fentanyl) sublingual tablets

Orexo
Galena Biopharma

Mar 18 2013

Asset purchase agreement for Abstral (fentanyl) sublingual tablets

Companies:	Orexo Galena Biopharma
Announcement date:	Mar 18 2013
Deal value, US$m:	15 : sum of upfront payments

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Details

Announcement date:	Mar 18 2013
Industry sectors:	Biotech Pharmaceutical Specialty pharma
Brand name:	Abstral
Therapy areas:	Oncology » Symptoms » Cancer pain
Technology types:	Drug delivery » Transmucosal » Sublingual Small molecules
Deal components:	Asset purchase Licensing
Stages of development:	Marketed
Geographic focus:	North America » United States

Financials

Deal value, US$m:	15 : sum of upfront payments
Upfront, US$m:	10 : sum of upfront payment 5 : sum of payments within first twelve months of closing
Milestones, US$m:	n/d : one time milestone payments
Royalty rates, %:	n/d : double-digit royalties on annual sales

Termsheet

Galena Biopharma has entered into an agreement with Orexo to acquire Abstral(fentanyl) Sublingual Tablets for sale and distribution in the United States.

Abstral is an important new treatment option for inadequately controlled breakthrough cancer pain in patients who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain.

Under the terms of the agreement, Galena Biopharma will pay Orexo $10 million upfront and $5 million within the first twelve months of closing, plus low double digit royalties and one-time milestone payments based on pre-specified net sales.

Press Release

Orexo AB Announces Divestiture of Abstral in the U.S. for $10 Million Upfront

3/18/2013 7:01:45 AM

LAKE OSWEGO, Ore., March 18, 2013 (GLOBE NEWSWIRE) -- Galena Biopharma, Inc. (GALE), a biopharmaceutical company developing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care, today announced it has entered into an agreement with Orexo AB (ORX.ST), an emerging specialty pharmaceutical company based in Sweden, to acquire Abstral(R) (fentanyl) Sublingual Tablets for sale and distribution in the United States.

Abstral is an important new treatment option for inadequately controlled breakthrough cancer pain (BTcP) in patients who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. BTcP has been shown to affect as many as 40-80 percent of cancer patients, with reported episodes of 4 per day and a median duration of 30 minutes. The innovative Abstral formulation delivers the analgesic power of fentanyl in a convenient and easy to use sublingual tablet, which dissolves under the tongue within seconds. Abstral provides rapid relief of BTcP, predictable dosing, and is convenient and easy to use.

Abstral was approved by the U.S. Food and Drug Administration (FDA) in January 2011; and, it is the transmucosal immediate-release fentanyl (TIRF) market leader in Europe where it achieved sales of $54 million by ProStrakan/Kyowa Hakko Kirin in 2012. It is marketed in Canada by Paladin Labs, and has been filed for approval in Japan by Kyowa Hakko Kirin, Co. Ltd. In 2012, the U.S. market for TIRFs was $400 million.

"The acquisition of Abstral diversifies and strengthens our pipeline, providing Galena with an FDA approved product that will become a cornerstone of our commercial strategy and bring revenues to the Company in 2014 to support the development of our pipeline," said Mark J. Ahn, Ph.D., President and Chief Executive Officer of Galena Biopharma. "Galena's launch of Abstral will build relationships with future prescribers of NeuVax(TM), which is currently in global Phase 3 clinical trials in node positive HER2 IHC 1+/2+ breast cancer patients. Medical oncologists, who manage tumor and treatment related pain, predominantly prescribe TIRFs for advanced breast cancer and other solid tumor patients which represent the majority of overall prescriptions."

Under the terms of the agreement, Galena Biopharma will pay Orexo $10 million upfront and $5 million within the first twelve months of closing, plus low double digit royalties and one-time milestone payments based on pre-specified net sales.

Galena has identified its commercialization management team towards a launch in the fourth quarter of 2013. To fund the acquisition and launch of Abstral, Galena plans to enter into a debt financing, subject to customary closing conditions. The term loan would include a total loan amount of $15 million, to be drawn in two tranches. Terms would include a coupon rate of approximately 7.59 percent and 4.5 percent warrant coverage. Interest-only payments would be due monthly through April 2014, then 30 months of amortization to maturity in 2016. The actual terms of the proposed debt financing may be different.

"With Galena Biopharma, Orexo has found a very committed partner for Abstral in the United States, who is well positioned to realize the significant potential that exists for Abstral. I have been impressed by the competence, experience and commitment to Abstral from the Galena Biopharma management team," stated Nikolaj Soerensen, President and CEO of Orexo.

About Breakthrough Cancer Pain

Breakthrough cancer pain is defined as a transient exacerbation of pain that occurs either spontaneously, or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background pain. Breakthrough cancer pain occurs in 40-80 percent of patients who are already receiving chronic, long-acting opioid pain management and yet have episodes of severe tumor- and treatment-related cancer pain. Breakthrough pain occurs frequently in these patients, particularly as they try to conduct normal daily activities, with a mean number of episodes of 4 per day (average range 1-14 per day) and a median duration of 30 minutes (range 1-240 minutes). The wide range of time to relief of these severe pain episodes leads to high levels of distress and impaired quality of life experienced by patients.

About Abstral(R) (fentanyl) Sublingual Tablets

Abstral(R) is an important new treatment option for inadequately controlled breakthrough cancer pain (BTcP) in opioid-tolerant cancer patients. The innovative Abstral formulation delivers the analgesic power of fentanyl in a convenient and easy to use sublingual tablet, which dissolves under the tongue within seconds. Abstral provides rapid relief of BTcP, predictable dosing, and is convenient and easy to use.

Abstral was approved by the FDA in 2011. Abstral is a sublingual (under the tongue) fentanyl tablet indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain. Abstral was evaluated in 311 opioid-tolerant cancer patients with breakthrough pain. Of these patients, 270 were treated in multiple-dose studies. The duration of therapy for patients in multiple-dose studies ranged from 1-405 days with an average duration of 131 days and with 44 patients treated for at least 12 months.

Formulated as rapidly disintegrating muco-adhesive sublingual tablets, Abstral is highly lipophilic with the fentanyl release from the tablet almost instantly. It is highly potent, crossing the blood-brain barrier rapidly, avoiding first-pass metabolism by the liver enzymes, and therefore offering high bioavailability. Moreover, the time-effect profile of Abstral closely matches the time-intensity profile of breakthrough cancer pain episodes; and the pharmacokinetics of Abstral have been shown to be dose-proportional over the dose range of 100ug to 800ug.

Common adverse reactions include nausea, constipation, drowsiness and headache. Serious adverse events, including deaths, have been reported in patients with other immediate-release transmucosal fentanyl products and occurred as a result of improper patient selection and/or improper dosing.

Abstral is available only through the transmucosal immediate-release fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) program, which is intended to minimize the risk of misuse, abuse, addiction and overdose. The FDA has standardized key components of the REMS program to facilitate the adoption of a single shared system. These components include the REMS document, the Patient-Prescriber Agreement, and the enrollment form.

About Orexo AB

Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations. The company has a portfolio of revenue generating EU and US approved products currently marketed under license and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB is headquartered in Sweden has 90 employees and is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap. For information about Orexo please visit www.orexo.com

About Galena Biopharma

Galena Biopharma, Inc. (GALE) is a Portland, Oregon-based biopharmaceutical company developing innovative, targeted oncology treatments that address major unmet medical needs to advance cancer care. For more information please visit us at www.galenabiopharma.com

Filing Data

Not available.

Contract

Not available.