Current Agreements

Dealdoc

Licensing agreement for bempedoic acid

Daiichi Sankyo
Esperion Therapeutics

Jan 04 2019

Licensing agreement for bempedoic acid

Companies:	Daiichi Sankyo Esperion Therapeutics
Announcement date:	Jan 04 2019
Amendment date:	Jan 03 2024
Deal value, US$m:	900 : sum of upfront and milestone payments

Details

Announcement date:	Jan 04 2019
Amendment date:	Jan 03 2024
Industry sectors:	Bigpharma Pharmaceutical
Brand name:	NILEMDO, NUSTENDI
Compound name:	Bempedoic acid
Exclusivity:	Exclusive
Asset type:	Compound
Therapy areas:	Cardiovascular » Hypercholesterolemia Hematology
Technology types:	Small molecules
Deal components:	Licensing
Stages of development:	Phase III
Geographic focus:	Europe

Financials

Deal value, US$m:	900 : sum of upfront and milestone payments
Upfront, US$m:	150 : upfront payment
Milestones, US$m:	n/d : substantial additional regulatory milestone payment upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, depending on the range of relative risk reduction in the CLEAR Outcomes study 150 : sales milestone payments 600 : additional milestone payments
Royalty rates, %:	n/d : tiered royalties on net territory sales

Termsheet

January 2024

Esperion Therapeutics and Daiichi Sankyo Europe GmbH announced a $125 million amendment to their collaboration, which includes an amicable resolution to their commercial dispute and certain other adjustments to enhance the long-term value of their products.

DSE has agreed to pay Esperion $100 million in mid-January ahead of an anticipated Type II(a) variation approval by the European Medicines Agency for NILEMDO (bempedoic acid) Tablet and NUSTENDI (bempedoic acid and ezetimibe) Tablet.

DSE will make an additional $25 million payment to Esperion in the calendar quarter immediately following EMA's decision on the pending application. The legal action pending in the United States District Court for the Southern District of New York will be dismissed.

The parties also agreed, as part of the resolution:

for Esperion to transition to DSE manufacturing and supply responsibilities in Europe and other territories, resulting in significant cost savings and efficiencies for both companies.

to expand their collaboration in Europe and other territories, to include the potential development and commercialization of a triple formulation product comprising bempedoic acid, ezetimibe and a statin, which could represent significant long-term value for the collaboration.

for DSE to now lead all regulatory communications with the EMA regarding the pending applications.

January 2019

Esperion Therapeutics have entered into a licensing agreement with Daiichi Sankyo Europe providing DSE with exclusive rights to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland.

The agreement combines Esperion Therapeutics' first-in-class ATP Citrate Lyase (ACL) inhibitor, bempedoic acid, with Daiichi Sankyo's European commercial capabilities which includes more than 1000 professionals dedicated to the commercialization of cardiovascular (CV) products, as well as synergies with their existing portfolio of novel oral anticoagulant and antiplatelet products.

This agreement seeks to distribute bempedoic acid and the bempedoic acid / ezetimibe combination pill to the millions of patients in these geographies that need additional low-density lipoprotein cholesterol (LDL-C) lowering after maximum tolerated statin therapy.

Esperion will grant Daiichi Sankyo Europe exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland.

Daiichi Sankyo Europe will be responsible for commercialization in the territories.

Esperion will receive an upfront cash payment of $150 million as well as $150 million upon first commercial sales in the territory.

Esperion is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, depending on the range of relative risk reduction in the CLEAR Outcomes study.

Esperion is eligible to receive additional sales milestone payments.

Esperion will receive substantial tiered royalties on net territory sales.

Press Release

January 2024

Esperion and Daiichi Sankyo Europe Announce $125 Million Amendment to Their Collaboration, Including Resolution of Pending Litigation

Near term payment to Esperion of $100 million plus $25 million in calendar quarter following EMA's expected decision on Type II(a) variation approval of NILEMDO® (bempedoic acid) Tablet and NUSTENDI® (bempedoic acid and ezetimibe) Tablet

Amendment also includes transfer of certain manufacturing and supply rights to DSE and expansion of collaboration in Europe and other territories

ANN ARBOR, Mich. and MUNICH, Germany, Jan. 03, 2024 (GLOBE NEWSWIRE) -- Esperion Therapeutics, Inc. (NASDAQ: ESPR) and Daiichi Sankyo Europe GmbH (DSE), the European headquarter organization of the Japanese pharmaceutical company Daiichi Sankyo Co., Ltd. (TSE: 4568), announced today a $125 million amendment to their collaboration, which includes an amicable resolution to their commercial dispute and certain other adjustments to enhance the long-term value of their products.

DSE has agreed to pay Esperion $100 million in mid-January ahead of an anticipated Type II(a) variation approval by the European Medicines Agency (EMA) for NILEMDO® (bempedoic acid) Tablet and NUSTENDI® (bempedoic acid and ezetimibe) Tablet. DSE will make an additional $25 million payment to Esperion in the calendar quarter immediately following EMA's decision on the pending application. The legal action pending in the United States District Court for the Southern District of New York will be dismissed.

The parties also agreed, as part of the resolution:

for Esperion to transition to DSE manufacturing and supply responsibilities in Europe and other territories, resulting in significant cost savings and efficiencies for both companies. to expand their collaboration in Europe and other territories, to include the potential development and

commercialization of a triple formulation product comprising bempedoic acid, ezetimibe and a statin, which could represent significant long-term value for the collaboration. for DSE to now lead all regulatory communications with the EMA regarding the pending applications. “We are pleased that this settlement creates value for Esperion today through cash payments and includes additional terms that will continue creating value for both companies going forward. Importantly, today’s settlement allows Esperion and DSE to focus on the business at hand – delivering life-saving drug therapies to millions with high cholesterol,” said Sheldon Koenig, Esperion’s President and CEO. “Together, we are committed to making bempedoic acid a blockbuster franchise worldwide, based on the differentiating profiles of our products.”

“This is a positive resolution for patients. We look forward to continuing to apply our combined strengths around the world to bring innovative pharmaceutical products to patients with cardiovascular disease, the greatest cause of death and disability globally,” said Oliver Appelhans, Head of the Specialty Business Unit of Daiichi Sankyo Europe.

Since 2019, Esperion and DSE have worked together to bring bempedoic acid to the eligible patient population and unlock its potential for cardiovascular risk reduction. The partnership continues to grow, with DSE recently gaining approvals for bempedoic acid in the Netherlands, Slovakia, and Spain.

About Esperion Therapeutics At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life’s work. For more information, visit esperion.com and esperionscience.com and follow us on X at twitter.com/EsperionInc.

About Daiichi Sankyo Daiichi Sankyo is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops, and delivers new standards of care to enrich the quality of life around the world. With more than 120 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular and other diseases with high unmet medical need. For more information, please visit www.daiichi-sankyo.eu.

January 2019

Esperion Announces Agreement with Daiichi Sankyo Europe (DSE) to Commercialize Bempedoic Acid in Europe

ANN ARBOR, Mich., (GLOBE NEWSWIRE) --Esperion Therapeutics Inc.(NASDAQ: ESPR) today announced that they have entered into a licensing agreement with Daiichi Sankyo Europe (DSE) providing DSE with exclusive rights to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland. The agreement combines Esperion Therapeutics’ first-in-class ATP Citrate Lyase (ACL) inhibitor, bempedoic acid, with Daiichi Sankyo’s European commercial capabilities which includes more than 1000 professionals dedicated to the commercialization of cardiovascular (CV) products, as well as synergies with their existing portfolio of novel oral anticoagulant and antiplatelet products. This agreement seeks to distribute bempedoic acid and the bempedoic acid / ezetimibe combination pill to the millions of patients in these geographies that need additional low-density lipoprotein cholesterol (LDL-C) lowering after maximum tolerated statin therapy.

“Daiichi Sankyo is focused on innovative pharmaceutical products to address the unmet medical needs of patients including those with cardiovascular disease, the number one cause of death and disability globally,” Ralf Goeddertz, Head of Business Development and Licensing at Daiichi Sankyo Europe. “The Esperion team has conducted a robust, 4,000 patient, high-quality development program to establish bempedoic acid as an efficacious and safe therapeutic option that will help millions of patients that do not reach LDL-C treatment goals.”

“We are very pleased to partner with DSE to establish bempedoic acid as the most preferred LDL-C lowering treatment option after statins for patients and physicians in Europe. Daiichi Sankyo Europe’s 1000 person cardiovascular commercial organization has a strong history of successfully commercializing drugs, including their novel oral anticoagulant, LIXIANA®, and there is significant overlap among physicians targeted for bempedoic acid,” said Tim Mayleben, president and chief executive officer of Esperion. “This agreement represents the first step in the evolution of Esperion from a pioneering development-stage company to a successful commercial-stage company.”

Esperion completed its Phase 3 LDL-C development program of bempedoic acid and the bempedoic acid / ezetimibe combination pill in October 2018. The company plans to submit New Drug Applications (NDAs) to the Food and Drug Administration (FDA) during the first quarter of 2019 and Marketing Authorization Applications (MAAs) to the European Medicines Agency (EMA) during the second quarter of 2019. FDA and EMA LDL-C approval decisions are expected during the first half of 2020. The global cardiovascular outcomes trial of bempedoic acid, CLEAR Outcomes, is ongoing and cardiovascular risk reduction results are expected during 2022.

Details of the Agreement and Financial Terms

Under the terms of the licensing agreement, Esperion will grant Daiichi Sankyo Europe exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination pill in the European Economic Area and Switzerland. Daiichi Sankyo Europe will be responsible for commercialization in the territories.

Esperion will receive an upfront cash payment of $150 million as well as $150 million upon first commercial sales in the territory. Esperion is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the Marketing Authorization in the EU for the CV Risk Reduction Label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, Esperion is eligible to receive additional sales milestone payments. Finally, Esperion will receive substantial tiered royalties on net territory sales.

Conference Call and Webcast Information

Esperion's Lipid Management Team will host a conference call and webcast today, Friday, January 4, 2019 at 8:00 a.m. Eastern Time to discuss the details of the agreement with Daiichi Sankyo Europe. The call can be accessed by dialing (877) 312-7508 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 5399439. A live audio webcast can be accessed on the investors and media section of the Esperion website at investor.esperion.com. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 90 days.

Bempedoic Acid / Ezetimibe Combination Pill

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP Citrate Lyase by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 (NPC1L1) by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn up-regulates the LDL receptors. Phase 3 data demonstrated that this safe and well tolerated combination results in a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ATP Citrate Lyase

inhibitor that, reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 2 and Phase 3 studies conducted in almost 4,800 patients, and approximately 3,100 patients treated with bempedoic acid, have produced an additional 20 percent LDL-C lowering when used with maximally tolerated statins, up to 30 percent LDL-C lowering as monotherapy, 35 percent LDL-C lowering in combination with ezetimibe when used with maximally tolerated statins and up to 48 percent LDL-C lowering in combination with ezetimibe as monotherapy.

The effect of bempedoic acid on cardiovascular morbidity and mortality has not yet been determined. The company initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and considered "statin intolerant." The CVOT — known as CLEAR Outcomes — is an event-driven, global, randomized, double-blind, placebo-controlled study expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at over 1,000 sites in approximately 30 countries.

About Esperion

Esperion is the Lipid Management Company passionately committed to developing and commercializing convenient, complementary, costeffective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease; the leading cause of death around the world. Bempedoic acid and the company's lead product candidate, the bempedoic acid / ezetimibe combination pill, are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies. For more information, please visit www.esperion.com and follow us on Twitter at https://twitter.com/EsperionInc.

Filing Data

Not available.

Contract

Not available.