Current Agreements

Dealdoc

Licensing and supply agreement for JUXTAPID

Aegerion Pharmaceutical
Recordati

Feb 06 2019

Licensing and supply agreement for JUXTAPID

Companies:	Aegerion Pharmaceutical Recordati
Announcement date:	Feb 06 2019
Deal value, US$m:	105 : sum of upfront and milestone payments

Details

Announcement date:	Feb 06 2019
Industry sectors:	Biotech Pharmaceutical
Brand name:	JUXTAPID
Compound name:	Lomitapide
Exclusivity:	Exclusive
Asset type:	Product
Therapy areas:	Cardiovascular » Hypercholesterolemia
Technology types:	Small molecules
Deal components:	Licensing
Stages of development:	Marketed
Geographic focus:	Asia » Japan

Financials

Deal value, US$m:	105 : sum of upfront and milestone payments
Upfront, US$m:	25 : upfront payment
Milestones, US$m:	80 : commercial milestone payments of up to
Royalty rates, %:	22.5 : royalty on net sales

Termsheet

Aegerion Pharmaceuticals has entered into an exclusive licensing agreement with Recordati Rare Diseases for the commercialization of JUXTAPID (lomitapide) in Japan.

The agreement includes exclusive rights in Japan for Recordati to commercialize JUXTAPID for the current approved indication, homozygous familial hypercholesterolemia (HoFH), and Aegerion grants Recordati an exclusive right of first negotiation for product commercialization in Japan of any potential new indications that may be developed by Aegerion.

Aegerion will receive a $25 million upfront payment, and an additional $5 million upon transfer of the JUXTAPID marketing authorization in Japan to Recordati.

Commercial milestone payments of up to an additional $80 million in the aggregate may become payable to Aegerion in prescribed increments, beginning at the end of the first quarter in which cumulative net sales in Japan reach $70 million, and continuing for each increase in cumulative net sales of $70 million thereafter, until cumulative net sales in Japan reach $700 million.

Recordati will also pay Aegerion on a quarterly basis a 22.5% royalty on net sales of JUXTAPID in Japan.

Press Release

Novelion Therapeutics Subsidiary Enters Into Licensing Agreement for JUXTAPID® in Japan

Out-licensing of commercialization rights allows for significant operating expense savings

Upfront payments improve near-term liquidity

VANCOUVER, British Columbia, Feb. 06, 2019 (GLOBE NEWSWIRE) -- Novelion Therapeutics Inc. (NASDAQ:NVLN), a biopharmaceutical company dedicated to developing new standards of care for individuals living with rare metabolic diseases (“Novelion”), announced that its subsidiary, Aegerion Pharmaceuticals, Inc. (“Aegerion”), has entered into an exclusive licensing agreement with Recordati Rare Diseases Inc. (“Recordati”) for the commercialization of JUXTAPID® (lomitapide) in Japan. The agreement includes exclusive rights in Japan for Recordati to commercialize JUXTAPID for the current approved indication, homozygous familial hypercholesterolemia (HoFH), and Aegerion grants Recordati an exclusive right of first negotiation for product commercialization in Japan of any potential new indications that may be developed by Aegerion.

“The licensing agreement for JUXTAPID in Japan is a positive step forward as we work to improve our near-term liquidity, reduce our operating expenses, and focus our efforts and resources with the goal of completing a comprehensive capital restructuring and creating a sustainable, cash-generating business,” said Ben Harshbarger, interim chief executive officer. “We believe Japan is an important market for JUXTAPID with meaningful potential for growth. Recordati has proven commercial capabilities and we are confident in their ability to deliver JUXTAPID to HoFH patients in need.”

Under the terms of the agreement, Aegerion will receive a $25 million upfront payment, and an additional $5 million upon transfer of the JUXTAPID marketing authorization in Japan to Recordati. Commercial milestone payments of up to an additional $80 million in the aggregate may become payable to Aegerion in prescribed increments, beginning at the end of the first quarter in which cumulative net sales in Japan reach $70 million, and continuing for each increase in cumulative net sales of $70 million thereafter, until cumulative net sales in Japan reach $700 million.

Recordati will also pay Aegerion on a quarterly basis a 22.5% royalty on net sales of JUXTAPID in Japan. Additional details pertaining to the agreement will be included in a Form 8-K to be filed by Novelion with the SEC, which can be accessed through the investor relations section of the Company’s website at https://ir.novelion.com/financial-information/sec-filings.

JUXTAPID was approved in September 2016 by Japan’s Ministry of Health, Labor & Welfare (MHLW) for patients with homozygous familial hypercholesterolemia (HoFH). HoFH is a serious, rare genetic disease that impairs the function of the receptor responsible for removing LDL-C (“bad” cholesterol) from the body. A loss of LDL receptor function results in extreme elevation of blood cholesterol levels. HoFH patients often develop premature and progressive atherosclerosis, a narrowing or blocking of the arteries.

Moelis & Company LLC acted as financial advisor to Aegerion in connection with the transaction.

About Novelion Therapeutics

Novelion, through Aegerion, is a global biopharmaceutical company dedicated to developing and commercializing therapies that deliver new standards of care for people living with rare and underserved metabolic diseases. Our goal is to develop and bring to market transformational therapies that have the potential to significantly change the treatment paradigm for patients affected by a variety of rare and metabolic diseases, including diseases associated with low leptin, such as low-leptin associated obesity. With a global footprint and an established commercial portfolio, including MYALEPT® (metreleptin) and JUXTAPID® (lomitapide), our business is supported by differentiated treatments that treat severe and rare diseases.

Novelion is the parent company of Aegerion, our operating subsidiary. References to “we,” “our” and the “Company” refer to the entire enterprise, whose assets and operations reside at Aegerion.

U.S. INDICATIONS AND IMPORTANT SAFETY INFORMATION

JUXTAPID® (lomitapide) capsules is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce LDL cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia (HoFH). LIMITATIONS OF USE: The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

JUXTAPID can cause elevations in transaminases, as well as increases in hepatic fat, with or without concomitant increases in transaminases. Because of the risk of hepatotoxicity, JUXTAPID is available only through a restricted distribution program called the JUXTAPID REMS PROGRAM. For more detailed information, please see additional Important Safety Information and the Prescribing Information for JUXTAPID.

Filing Data

On February 5, 2019 (the “Effective Date”) Aegerion Pharmaceuticals, Inc. (the “Company”), a subsidiary of Novelion Therapeutics Inc. (“Novelion”), entered into a license agreement (the “License Agreement”) with Recordati Rare Diseases Inc. (“Recordati”) for the commercialization of JUXTAPID® (lomitapide) in Japan. Under the terms of the License Agreement, and subject to the conditions set forth therein, the Company granted to Recordati an exclusive license in Japan, with the right to grant sub-licenses, to manufacture and commercialize the Company’s current JUXTAPID product that contains lomitapide as the sole active ingredient (the “Product”), for the current marketed indication for homozygous familial hypercholesterolemia (HoFH). During the term of the License Agreement, Recordati also has an exclusive right of first negotiation to any new indications for the Product in Japan.

Pursuant to the terms of the License Agreement, and subject to the conditions set forth therein, Recordati is required to make the following payments to the Company: (i) $25 million as a one-time upfront payment on the Effective Date, (ii) $5 million as a one-time payment within 45 days following the date on which the Japan marketing authorization for the Product is successfully transferred to Recordati (the “Completion Date”), (iii) quarterly royalty payments, during the term of the License Agreement, equal to 22.5% of all net sales of the Product in Japan, and (iv) 20% of all other sublicense revenues received by Recordati or any of its affiliates.

In addition, pursuant to the terms of the License Agreement, the Company may receive from Recordati commercial milestone payments (up to a total of $80 million) for net sales in Japan, conditioned and based upon the achievement of certain net sales levels in Japan, the first $12.5 million installment of which becomes payable at the end of the first quarter in which cumulative net sales in Japan reach $70 million, and which are payable in increments thereafter at the end of each quarter in which cumulative net sales in Japan increase by $70 million (in increments of $12.5 million until cumulative net sales reach $280 million and then in increments of $5 million until cumulative net sales reach $700 million).

Pursuant to the terms of the Company’s bridge credit agreement (the “Bridge Loan”), dated November 8, 2018, with certain funds of Athyrium Capital Management, LP (“Athyrium”) and Highbridge Capital Management, LLC (“Highbridge” and together with Athyrium, the “Lenders”), $15 million of the upfront payment will be paid to the Company, and the remaining net cash proceeds will be paid to Novelion to repay a portion of the outstanding intercompany loan and to the Lenders to repay a portion of the outstanding Bridge Loan, on a 42% and 58% basis, respectively. Further, under the Company’s current license agreement with the University of Pennsylvania (“UPenn”), UPenn is entitled to 15% of the $25 million upfront payment, as well as 15% of the marketing authorization transfer milestone and any subsequent sales milestone payments, received from Recordati.

The Company and Recordati have made customary representations and warranties and have agreed to certain other customary covenants, including confidentiality, limitation of liability and indemnity provisions.

The Company and Recordati have also entered into a customary supply agreement under which the Company will supply the Product to Recordati (or its affiliate) at cost plus an agreed upon markup for an initial term of two years with automatic renewal for successive two year terms, and a customary transitional services agreement under which the Company will continue to perform certain commercialization and administrative services on Recordati’s behalf until the Completion Date (during which time, in lieu of paying royalties and cost-plus supply and transitional services during this period, the Company will retain 40% of the net sales of Product in Japan and remit the remaining 60% of net sales to Recordati) and certain other customary transitional services (if so requested by Recordati) at mutually agreed hourly rates for a term not to exceed six months from the Completion Date.

The initial term of the License Agreement continues until the latest of: (i) expiration of the last valid claim of the licensed patents covering the Product in Japan, (ii) expiration of data or regulatory exclusivity in relation to the Product in Japan, or (c) ten years from the Completion Date. Thereafter the term of the License Agreement will automatically renew for a single five-year term, and then thereafter for successive five-year terms unless either party provides written notice at least 18 months prior to the end of the then current renewal term. Either party may terminate the License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for 90 days (15 days for non-payment).

The foregoing is only a summary of the material terms of the License Agreement and does not purport to be a complete description of the rights and obligations of the parties under such agreement. The foregoing summary is qualified in its entirety by reference to the License Agreement, which Novelion expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2019.

Contract

Not available.