Current Agreements

Dealdoc

Licensing and supply agreement for captisol-enabled, propylene glycol-free melphalan

Ligand Pharmaceuticals
Spectrum Pharmaceuticals

Mar 14 2013

Licensing and supply agreement for captisol-enabled, propylene glycol-free melphalan

Companies:	Ligand Pharmaceuticals Spectrum Pharmaceuticals
Announcement date:	Mar 14 2013
Amendment date:	Mar 15 2016
Deal value, US$m:	50 : potential milestone payments

Details

Announcement date:	Mar 14 2013
Amendment date:	Mar 15 2016
Industry sectors:	Bigbiotech Biotech Drug delivery
Compound name:	Melphalan
Therapy areas:	Hospital care » Palliative care Oncology Oncology » Multiple myeloma
Technology types:	Adjuvant Drug delivery » Targeted Enabling technology Radio/Chemo-therapy Regenerative medicine » Cell therapy
Deal components:	Licensing Supply
Geographic focus:	Worldwide

Financials

Deal value, US$m:	50 : potential milestone payments
Upfront, US$m:	n/d : license fee
Milestones, US$m:	50 : potential milestone payments
Royalty rates, %:	n/d : based on future sales
More details:	Ligand is entitled to receive a license fee.

Termsheet

15 March 2016

Ligand Pharmaceuticals Incorporated announces that Spectrum Pharmaceuticals, Inc., a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, received approval from the U.S. Food and Drug Administration (FDA) of EVOMELA™ (melphalan) for use in two indications: 1) as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation (ASCT) in patients with MM, and 2) for the palliative treatment of patients with MM for whom oral therapy is not appropriate.

Spectrum Pharmaceuticals licensed global development and commercialization rights to EVOMELA from Ligand Pharmaceuticals in March 2013.

Spectrum assumed responsibility for completing the pivotal Phase 2 clinical trial, and was responsible for filing the New Drug Application (NDA).

Under the license agreement, Ligand received an upfront fee and earned a $6 million milestone payment on EVOMELA approval, as well as royalties on net sales.

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14 March 2013

Ligand Pharmaceuticals announces the signing of global license and supply agreements with Spectrum Pharmaceuticals for the development and commercialization of Ligand's Captisol-enabled, propylene glycol-free (PG-free) melphalan.

Ligand is entitled to receive a license fee and is eligible to receive more than $50 million in potential milestone payments.

Ligand is also eligible to receive royalties on future net sales of Captisol-enabled melphalan.

The Captisol-enabled melphalan program is currently in a pivotal trial for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma.

Spectrum will immediately assume all development of the program as a result of this license.

Press Release

15 March 2016

Ligand Pharmaceuticals Incorporated announces that Spectrum Pharmaceuticals, Inc., a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, received approval from the U.S. Food and Drug Administration (FDA) of EVOMELA™ (melphalan) for use in two indications: 1) as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation (ASCT) in patients with MM, and 2) for the palliative treatment of patients with MM for whom oral therapy is not appropriate.

Spectrum Pharmaceuticals licensed global development and commercialization rights to EVOMELA from Ligand Pharmaceuticals in March 2013.

Spectrum assumed responsibility for completing the pivotal Phase 2 clinical trial, and was responsible for filing the New Drug Application (NDA).

Under the license agreement, Ligand received an upfront fee and earned a $6 million milestone payment on EVOMELA approval, as well as royalties on net sales. About Multiple Myeloma Multiple myeloma is a systemic malignancy of plasma cells that accumulate in the bone marrow, usually associated with monoclonal antibody secretion, and results in bone marrow failure and bone destruction. It is the second most common hematologic disease with nearly 30,000 new cases projected in the U.S. in 2016 and more than 11,000 deaths annually (American Cancer Society Stats, 2016). The rate of ASCT for patients with MM is growing by approximately 3.3% annually. Melphalan is the most commonly used IV agent for high-dose conditioning for patients undergoing ASCT for MM. The current IV melphalan market is approximately $100 million annually, with predominant use in ASCT; EVOMELA is the only intravenous melphalan product that is approved for use in the high-dose conditioning indication. About EVOMELA™ EVOMELA was approved by the FDA based on its bioequivalence to the standard melphalan formulation (Alkeran) in a Phase 2 clinical study (Aljitawi et al., Bone Marrow Transplant, 2014) via the 505(b)(2) regulatory pathway. EVOMELA has been granted Orphan Drug Designation by the FDA for its use as a high-dose conditioning regimen for patients with MM undergoing ASCT. EVOMELA's new melphalan formulation does not contain propylene glycol. The use of the Captisol® technology to reformulate also contributes to the 4-hour admixture stability of EVOMELA at room temperature. This is in addition to the 1-hour stability of reconstituted EVOMELA drug product at room temperature and 24-hour stability at stability at refrigerated temperature (5°C).

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14 March 2013

Ligand Pharmaceuticals Inc. (LGND) Lifts '13 Outlook; Signs a License Deal With Spectrum Pharmaceuticals, Inc. (SPPI)

3/14/2013 7:26:19 AM

SAN DIEGO--(BUSINESS WIRE)-- Ligand Pharmaceuticals Incorporated (LGND) announces the signing of global license and supply agreements with Spectrum Pharmaceuticals, Inc. (SPPI) for the development and commercialization of Ligand's Captisol-enabled®, propylene glycol-free (PG-free) melphalan. Under the terms of the license agreement, Ligand is entitled to receive a license fee and is eligible to receive more than $50 million in potential milestone payments. Ligand is also eligible to receive royalties on future net sales of Captisol-enabled melphalan. Further details regarding the transaction are provided in Ligand's Form 8-K that is being filed today.

The Captisol-enabled melphalan program is currently in a pivotal trial for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma. Spectrum will immediately assume all development of the program as a result of this license.

“We are pleased to have forged this agreement,” commented John Higgins, President and Chief Executive Officer of Ligand Pharmaceuticals. “Spectrum has an established oncology and hematology business, and this melphalan product is an ideal complement to their two commercial hematology products, Zevalin and Folotyn, including an expected high degree of commercial call overlap. Spectrum’s highly experienced, oncology-focused R&D team is committed to the efficient development of Captisol-enabled melphalan, and has established relationships with key investigators.”

Full Year 2013 Revenue and Earnings Guidance and First Quarter Forecast

Ligand now expects 2013 total revenues to be in the range of $43 million to $46 million, versus previous guidance of $41 million to $44 million. Earnings per share for 2013 are expected to be in the range of $0.47 to $0.51, versus previous guidance of $0.35 to $0.39. Ligand estimates revenue for the first quarter of 2013 to be in the range of $10 million to $11 million, with first quarter earnings per share in the range of $0.10 to $0.13. Earnings per share guidance does not include the effects of any increase or decrease in contingent liabilities.

About Captisol-enabled Melphalan

Ligand's Captisol-enabled, PG-free melphalan program is a new intravenous formulation of melphalan being investigated for the multiple myeloma transplant setting, and has been granted Orphan designation by the FDA. Ligand's formulation avoids the use of propylene glycol, which has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of therapeutic compounds. The use of the Captisol® technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to safely achieve a higher dose intensity of pre-transplant chemotherapy. In December 2012 Ligand announced the initiation of a pivotal trial of Captisol-enabled melphalan. This multi-center trial will evaluate safety and efficacy in 60 patients, and is intended to confirm the results from an earlier Phase 2 study demonstrating that the Captisol-enabled melphalan formulation was safe and well-tolerated, and met the requirements for establishment of bioequivalence to the current commercial intravenous formulation of melphalan (sold by GlaxoSmithKline as Alkeran® for Injection).

About Multiple Myeloma and Melphalan

Multiple myeloma is a cancer of plasma cells, a type of white blood cell present in the bone marrow. In multiple myeloma a group of plasma cells (myeloma cells) becomes cancerous and multiplies, raising the number of plasma cells to a higher-than-normal level. There are an estimated 20,000 new cases of multiple myeloma in the United States each year, with an incidence of new cases increasing by approximately 1.7% per year.

The current intravenous melphalan market is approximately $130 million annually, with predominant use in stem cell transplants. The rate of autologous stem cell transplants for patients with multiple myeloma is growing by approximately 3.3% annually.

About Captisol

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled six FDA-approved products, including Onyx Pharmaceuticals’ Kyprolis®, Baxter International's Nexterone® and Pfizer's Vfend® IV. There are currently more than 30 Captisol-enabled products in development, including Lundbeck’s carbamazepine IV, The Medicines Company's MDCO-157 and Rib-X's delafloxacin IV program.

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company that develops and acquires assets it believes will generate royalty revenues and, under its lean corporate cost structure, produce sustainable profitability. Ligand has a diverse asset portfolio addressing the unmet medical needs of patients for a broad spectrum of diseases including thrombocytopenia, multiple myeloma, diabetes, hepatitis, muscle wasting, dyslipidemia, anemia and osteoporosis. Ligand’s Captisol platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand has established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, Onyx Pharmaceuticals, Merck, Pfizer, Baxter International, Bristol-Myers Squibb, Celgene, Lundbeck Inc., Eli Lilly & Co., Spectrum Pharmaceuticals and The Medicines Company. Please visit www.captisol.com for more information on Captisol or www.ligand.com for more information on Ligand.

Filing Data

Not available.

Contract

Not available.