

## **SAMPLE DATA**

### **Cancer – Ceeplen® Leukemia Treatment**

**Licensor: EpiCept Corporation**

**Licensee: Meda AB**

**Royalty: \$3 million upfront fee plus double digit royalty percentage on sales**

EpiCept is focused on the development and commercialization of pharmaceutical products for the treatment of cancer and pain. The company's lead product is Ceplene, which has been granted full marketing authorization by the European Commission for the remission maintenance and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML) in first remission. The company has two oncology drug candidates currently in clinical development that were discovered using in-house technology and have been shown to act as vascular disruption agents in a variety of solid tumors. The company's pain portfolio includes EpiCept(TM) NP-1, a prescription topical analgesic cream in late-stage clinical development designed to provide effective long-term relief of pain associated with peripheral neuropathies.

EpiCept Corporation entered into an exclusive commercialization agreement for Ceplene (R) (histamine dihydrochloride) with Meda AB, a leading international specialty pharmaceutical company based in Stockholm. Ceplene is EpiCept's novel therapy approved in the European Union with orphan drug status for the remission maintenance and prevention of relapse of patients with acute myeloid leukemia (AML) in first remission.

Meda is a leading international specialty pharmaceutical company with products sold in 120 countries worldwide. The company has its own sales organizations in the U.S. and more than 40 other countries, including a marketing organization of about 1,200 people throughout Europe. Meda's annual sales is currently approximately \$1.8 billion with several products in the cancer area, including Onsolis(R), indicated for breakthrough pain in cancer patients.

Under the terms of the agreement, EpiCept will grant Meda the right to market Ceplene in Europe and several other countries including Japan, China, and Australia. EpiCept will receive a \$3 million fee and an additional \$2 million upon the first commercial launch of Ceplene in a major European market, which is expected later this year. Additional payments include a \$5 million payment upon achievement of a regulatory milestone and up to \$30 million in sales-based milestones that commence upon attainment of at least \$50 million in annual sales. EpiCept will receive a double digit percent royalty on net sales in the covered territories and will be responsible for Ceplene's commercial supply.

Ceplene is indicated for remission maintenance therapy and prevention of relapse in adult patients with Acute Myeloid Leukemia (AML). Ceplene is used together with low dose Interleukin-2. AML is one of four major types of leukemia. The prevalence for AML in the EU is about 41,000 patients and over 16,000 new cases are diagnosed every year. While current induction and consolidation treatments are successful in inducing complete remission for the majority of AML patients, this remission is generally short-lived. After achieving complete remission most patients will suffer a relapse within one year. In an international, multicenter, open-label, randomized phase III study, Ceplene met its primary endpoint of prolonging leukemia-free survival for AML patients in remission. Source: Press Release, EpiCept Announces Commercial Licensing Agreement for Ceplene® with Meda in Europe and Pacific Rim Agreement Includes Upfront Payment, Milestones and Product Royalties Tarrytown, NY., Jan 11, 2010 (Business Wire) - Regulatory News.

## **Fusion Inhibitors for HIV**

**Licensors: New York Blood Center**

**Licensee: Trimeris, Inc.**

**Royalty: 0.25% to 1% of sales**

Trimeris, Inc. is a biopharmaceutical company incorporated in 1993 and primarily engaged in the commercialization of a class of antiviral drug treatments called fusion inhibitors. Fusion inhibitors prevent viral fusion, a complex process by which viruses attach to, penetrate and infect host cells. If a virus cannot enter a host cell, the virus cannot replicate. By inhibiting the fusion process of particular types of viruses, like the Human Immunodeficiency Virus (“HIV”), Trimeris’s first commercial product, Fuzeon® (originally known as T-20), and our development-stage compound, TRI-1144, offer a novel mechanism of action to treat and potentially prevent the transmission of HIV.

Fuzeon is Trimeris’ first-generation HIV fusion inhibitor, developed in collaboration with F. Hoffmann-La Roche Ltd. (“Roche”). Fuzeon has been shown to inhibit HIV viral fusion with host cells by blocking the conformational rearrangement of an HIV protein called gp41. The Food and Drug Administration (the “FDA”) approved the use of Fuzeon in combination with other anti-HIV drugs for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing anti-HIV therapy. The FDA granted accelerated approval for the commercial sale of Fuzeon in 2003, and commercial sales of Fuzeon began in March that same year. Full approval was granted in October 2004. Roche also filed an application for European marketing approval of Fuzeon in September 2002 and was granted marketing approval under exceptional circumstances by the European Agency for the Evaluation of Medicinal Products in May 2003.

Roche is manufacturing Fuzeon drug substance in its Boulder, Colorado facility. Roche uses this drug substance to produce Fuzeon finished drug product at its manufacturing facility in Basel, Switzerland. Fuzeon is distributed and sold by Roche through Roche’s sales and distribution network throughout the world in countries where regulatory approval has been received.

Commercial sales of Fuzeon began in the United States in March 2003. Roche retained an exclusive license to manufacture and sell Fuzeon worldwide. Under Trimeris’ Development and License Agreement with Roche, Trimeris share profits equally from the sale of Fuzeon in the United States and Canada. During 2009, net sales of Fuzeon in the United States and Canada decreased 39% to \$39.1 million from \$64.2 million in 2008. Net sales were \$124.3 million in 2007. Net sales outside the United States and Canada decreased 29% to \$73.1 million in 2009 from \$102.8 million in 2008. Net sales outside the United States and Canada in 2007 were \$142.5 million. Unit sales of Fuzeon are expressed in kits shipped. A kit represents a one-month supply of Fuzeon for a patient. During 2009, Roche sold and shipped approximately 20,000 kits to wholesalers in the United States and Canada compared to 36,000 kits in 2008 and 72,200 kits in 2007. In addition, Trimeris agreed to pay Roche a low single-digit royalty on future net sales of its lead Next Generation Fusion Inhibitor (“NGFI”) candidate, TRI-1144, up to a specified limit.

Trimeris has an exclusive, worldwide, royalty-bearing license from the New York Blood Center (the “NYBC”) under certain U.S. and foreign patents and patent applications relating to certain HIV peptides. Under this license, the company is required to pay the NYBC a royalty in the amount equal to one-half of one percent of net sales (as defined in the license agreement) of Fuzeon sold by Trimeris, or by a sublicensee, in any calendar year, until such time as \$100 million of net sales is attained; after which the company will pay the NYBC a royalty in an amount equal to one-quarter of one percent of net sales of FUZEON sold by Trimeris and any

sublicensee in any calendar year in any country where the NYBC has a pending, or issued, unexpired and valid claim contained in the licensed patents. The obligation to pay royalties to the NYBC under the company's exclusive license to the patents ends on August 22, 2012. Trimeris recognized expense of approximately \$284,000, \$523,000, and \$758,000 during 2009, 2008, and 2007, respectively, for royalty payments due to the NYBC related to the sales of Fuzeon. Source: Trimeris, Inc. 2010 10K.

## **Modulation of Opioid Receptors**

**Licensors: Rensselaer Polytechnic Institute**

**Licensee: Alkermes, Inc.**

**Royalty: \$500,000 plus 1% to 4% of revenues**

Alkermes, Inc. leverages its formulation expertise and drug development technologies to develop, both with partners and on its own, innovative and competitively advantaged drug products that can enhance patient outcomes in major therapeutic areas. Alkermes enters into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating technologies. In addition, Alkermes applies its innovative formulation expertise and drug development capabilities to create their own new, proprietary pharmaceutical products.

In September 2006, Alkermes and Rensselaer Polytechnic Institute (RPI) entered into a license agreement granting Alkermes exclusive rights to a family of opioid receptor compounds discovered at RPI. These compounds represent an opportunity for Alkermes to develop therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders.

Under the terms of the agreement, RPI granted Alkermes an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. Alkermes is responsible for the continued research and development of any resulting product candidates. Alkermes paid RPI a nonrefundable upfront payment of \$0.5 million and is obligated to pay annual fees of up to \$0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, Alkermes is obligated to make milestone payments in the aggregate of up to \$9.1 million upon certain agreed-upon development events. In July 2008, the parties amended the agreement to expand the license to include certain additional patent applications. Alkermes paid RPI an additional nonrefundable payment of \$125,000 and slightly increased the annual fees in consideration of this amendment. Source: Alkermes, Inc. 2009 10K.