EXHIBIT 2013

Drugs.com
Know more. Be sure.

FDA Approves Treanda

Cephalon Receives FDA Approval for Treanda, a Novel Chemotherapy for Chronic Lymphocytic Leukemia

First New Agent for CLL Patients Approved by the FDA since 2001

FRAZER, Pa., March 20, 2008 /PRNewswire-FirstCall/ -- Cephalon, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved **Treanda** (bendamustine hydrochloride) for Injection for the treatment of patients with chronic lymphocytic leukemia (CLL), a slowly progressing blood and bone marrow disease. The American Cancer Society estimates that more than 15,000 new cases of this rare disease will be diagnosed in the United States this year. The Treanda application as a CLL treatment received priority review from the FDA and was approved within six months of the September 2007 submission. Cephalon anticipates that Treanda will be available to physicians and patients as a CLL treatment in the United States in April 2008.

"Treanda is an important new treatment for patients with chronic lymphocytic leukemia, and this first-cycle approval by FDA represents a significant milestone in the growth of our oncology business," said Dr. Lesley Russell, Executive Vice President, Worldwide Medical and Regulatory Operations. "With a strong pipeline of near- and longer-term opportunities, Cephalon Oncology is poised to deliver therapies that target both hematologic cancers and solid tumors for patients in need of new options."

Dr. Bruce Cheson, Clinical Professor of Hematology/Oncology, Georgetown University School of Medicine, Washington D.C., stated, "Patients with chronic lymphocytic leukemia can often live normal lives for many years because of treatments that control the disease over the long-term. Treanda is an effective new option that offers a delay in disease progression, an important goal for patients with chronic lymphocytic leukemia."

In a randomized, international, multicenter, open-label pivotal study of 301 treatment-naive patients with CLL, those who received Treanda had better clinical outcomes compared to patients treated with chlorambucil, an FDA-approved chemotherapy for patients with CLL. Specifically, Treanda patients had a significantly higher overall response (59 percent of patients responded to Treanda and 26 percent of patients responded to chlorambucil; $p < 0.0001$). Patients who received Treanda also had a higher complete response rate than those treated with chlorambucil (8 percent vs. <1 percent), which means that after treatment with Treanda, some patients had no signs of disease in their blood.

Importantly, Treanda patients also had a significantly longer progression- free survival (18 months vs. 6 months; Hazard Ratio = 0.27; $p < 0.0001$), meaning the disease did not get worse for a significant period of time. The response to Treanda lasted longer (duration of response) than in patients who received chlorambucil (19 months vs. 7 months). The most common adverse events in the trial were myelosuppression, fever, nausea, and vomiting.

Treanda has been granted orphan drug status by the FDA for the treatment of CLL. The orphan drug designation will provide marketing exclusivity in this indication until March 2015.

About Treanda

Treanda has a unique chemical structure with two primary components, an alkylating group and a benzimidazole component. Preclinical data suggest that Treanda can lead to cell death via several pathways. Treanda damages the DNA in cancer cells, which leads to cell death by a process known as apoptosis (programmed cell death) as well as by an alternate cell death (non-apoptotic) pathway known as mitotic catastrophe (a disruption of normal cell division). The exact mechanism of action of Treanda remains unknown.

In December 2007, Cephalon submitted an NDA requesting approval of Treanda for the treatment of patients with indolent (slow-growing) non-Hodgkin's lymphoma who have progressed during or following treatment with rituximab or a rituximab-containing regimen and anticipates a review decision by October 31, 2008. The protocol for the Treanda NHL pivotal trial received special protocol assessment (SPA) approval from the FDA in February 2006. The SPA process allows for FDA evaluation and acceptance of a clinical trial protocol, including trial size, clinical endpoints and/or data analysis.

Cephalon holds exclusive rights to market and develop Treanda in the United States. Treanda is licensed from Astellas Pharma GmbH. Bendamustine HCl, the active ingredient in Treanda, is marketed in Germany by Astellas' licensee, Mundipharma International Corporation Limited, under the tradename RIBOMUSTIN. In Germany, RIBOMUSTIN is indicated as a single-agent or in combination with other anti-cancer agents for indolent NHL, multiple myeloma, and CLL. SymBio Pharmaceuticals Ltd holds exclusive rights to develop and market bendamustine HCl in Japan and selected Asia Pacific Rim countries.

About Cephalon Oncology

Cephalon Oncology is a strategic business unit focused on the development and commercialization of oncology products and resources for patients and healthcare providers. The Cephalon Oncology portfolio includes a number of promising investigational and marketed compounds. In addition to Treanda, the Cephalon Oncology therapeutic portfolio in the United States includes TRISENOX (arsenic trioxide) injection, a product approved in the United States for the treatment of patients with relapsed or refractory acute promyelocytic leukemia, and CEP-701, an oral small molecule inhibitor of tyrosine kinases including FLT-3, TRK and JAK-2, in phase 3 development for acute myeloid leukemia.

In Europe, Cephalon markets three additional oncology products in 19 countries.

About Cephalon, Inc.

Founded in 1987, Cephalon, Inc. is an international biopharmaceutical company dedicated to the discovery, development and commercialization of innovative products in four core therapeutic areas: central nervous system, pain, oncology and addiction. A member of the Fortune 1000, Cephalon currently employs approximately 3,000 people in the United States and Europe. U.S. sites include the company's headquarters in Frazer, Pennsylvania, and offices, laboratories or manufacturing facilities in West Chester, Pennsylvania, Salt Lake City, Utah, and suburban Minneapolis, Minnesota. The company's European headquarters are located in Maisons-Alfort, France.

The company's proprietary products in the United States include: Provigil (modafinil) Tablets [C-IV], Fentora (fentanyl buccal tablet) [C-II], Trisenox (arsenic trioxide) injection, Treanda, Amrix (cyclobenzaprine hydrochloride extended-release capsules), Vivitrol (naltrexone for extended-release injectable suspension), Gabitril (tiagabine hydrochloride), Nuvigil (armodafinil) Tablets [C-IV] and Actiq

(oral transmucosal fentanyl citrate) [C-II]. The company also markets numerous products internationally. Full prescribing information on its U.S. products is available at **http://www.cephalon.com** or by calling 1-800-896-5855.

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Cephalon's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs; development of potential pharmaceutical products, including the results of any clinical programs with respect to Treanda or the timing or approval of any current or future filings for regulatory approval of Treanda or other Cephalon Oncology compounds; interpretation of clinical results, particularly with respect to the Treanda clinical trials; manufacturing development and capabilities; market prospects for its products, including the anticipated availability of Treanda in the United States or the benefits Treanda may provide; sales and earnings guidance; and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Cephalon's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries as well as more specific risks and uncertainties facing Cephalon such as those set forth in its reports on Form 8-K, 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Cephalon does not intend to update publicly any forward-looking statement, except as required by law. The Private Securities Litigation Reform Act of 1995 permits this discussion.

CONTACT: Media, Jenifer Antonacci, +1-610-738-6674, ;or Candace Steele, +1-610-727-6231, ; Investors, Robert'Chip' Merritt, +1-610-738-6376, **jantonac@cephalon.com csteele@cephalon.com cmerritt@cephalon.com**

Web site: **http://www.cephalon.com/**

Company News On-Call: **http://www.prnewswire.com/comp/134563.html** /

Ticker Symbol: (NASDAQ-NMS:CEPH)

Posted: March 2008

Related Articles:

- **Cephalon Receives FDA Approval for Treanda to Treat Patients with Relapsed Indolent Non-Hodgkin's Lymphoma** - November 3, 2008
- **FDA Accepts Treanda New Drug Application for the Treatment of Relapsed Indolent Non-Hodgkin's Lymphoma** - February 19, 2008
- **Cephalon Submits New Drug Application for Treanda for the Treatment of Patients with Relapsed Indolent Non-Hodgkin's Lymphoma** - January 2, 2008

- **Treanda New Drug Application for the Treatment of Chronic Lymphocytic Leukemia Granted Priority Review Status by FDA** - December 3, 2007
- **Cephalon Submits New Drug Application for Treanda for the Treatment of Chronic Lymphocytic Leukemia** - September 21, 2007
- **Cephalon Announces Plans for New NDA Filing for Treanda** - June 28, 2007

Treanda (bendamustine hydrochloride) FDA Approval History

View comments