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Treanda

Treatment for Chronic Lymphocytic Leukemia, non-Hodgkin's Lymphoma

Update: **Treanda** Now FDA Approved - March 20, 2008

Treanda New Drug Application for the Treatment of Chronic Lymphocytic Leukemia Granted Priority Review Status by FDA

FRAZER, Pa., December 03, 2007 /PRNewswire-FirstCall/ -- Cephalon, Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted priority review designation to the Treanda (bendamustine HCl) New Drug Application (NDA) for the first-line treatment of patients with chronic lymphocytic leukemia (CLL). CLL is a slowly progressing blood and bone marrow disease with an estimated 15,000 new cases diagnosed every year in the United States. Cephalon filed the Treanda NDA for CLL in September 2007 and the FDA will make a review decision by the end of March 2008.

"If approved, Treanda will make a meaningful difference as the first new CLL treatment option approved by the FDA since 2001 and could be available as soon as the second quarter of 2008," said Dr. Lesley Russell, Executive Vice President, Worldwide Medical and Regulatory Operations.

The FDA assigns priority review to drugs that, if approved, would offer major advances in treatment or would provide treatment to patients where no adequate therapy exists. Priority review reduces the targeted NDA review time from 10 months to six months. FDA granted orphan drug status for Treanda for CLL in August 2007, which would entitle Cephalon to a seven-year period of marketing exclusivity in the United States, if the product is approved for this indication.

About Treanda

Treanda is a rationally designed purine analog/alkylator hybrid. Preclinical data demonstrate that this rationally designed hybrid acts in two ways to kill cancer cells. Treanda damages the DNA in cancer cells, which leads to the normal path of cell death (apoptosis). It also stops cancer cells from dividing to create new cancer cells. This dual-action of Treanda may be attributable to its unique chemical design.

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 Asian countries.

Treanda in CLL

The Treanda NDA for the treatment of patients with CLL is based on a large, international multi-center Phase 3 clinical trial that evaluated the safety and efficacy of bendamustine HCl, the active ingredient in Treanda, compared to chlorambucil in patients who were not previously treated for their disease. Chlorambucil, a chemotherapy drug, is FDA-approved as a first-line therapy for patients with CLL. In the pivotal trial, bendamustine HCl met both primary endpoints -- overall response rate and progression-free survival -- and demonstrated a manageable tolerability profile. The company anticipates that results from this study will be released at the American Society of Hematology (ASH) annual meeting, which begins on December 8, 2007 in Atlanta, Georgia.

Treanda in NHL

The company has also studied Treanda for the treatment of patients with indolent non-Hodgkin's lymphoma (NHL) whose cancer is no longer responsive to treatment with rituximab. This study also met its primary endpoints of overall response rate and median duration of response, while demonstrating a manageable tolerability profile. The company anticipates filing an NDA in the fourth quarter of 2007 for Treanda in patients with indolent NHL who failed treatment with rituximab. In addition, Cephalon has studied Treanda in combination with rituximab in patients with relapsed indolent and mantle cell NHL. Results from these studies of Treanda as monotherapy and in combination will be presented at medical meetings later this year.

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.

Cephalon, Inc. is an international biopharmaceutical company, recently inducted into the World Economic Forum Community of Global Growth Companies. For 20 years, the company has been 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. Cephalon'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, AMRIX(TM) (cyclobenzaprine hydrochloride extended-release capsules), VIVITROL (naltrexone for extended-release injectable suspension), GABITRIL (tiagabine hydrochloride), NUVIGIL(TM) (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 acceptance 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; 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, Candace Steele, +1-610-727-6231, , orfor Investors, Robert (Chip) Merritt, +1-610-738-6376,, both of Cephalon, Inc. **csteele@cephalon.com cmerritt@cephalon.com**

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

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Treanda (bendamustine hydrochloride) FDA Approval History

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