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Cephalon Receives FDA Approval for Treanda to Treat Patients with Relapsed Indolent Non-Hodgkin's Lymphoma

FRAZER, Pa., Oct. 31, 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 indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The data supporting the FDA approval show that Treanda is effective, has a tolerable side effect profile in patients with indolent NHL and that treatment results in a high durable response rate. In March of this year, Treanda received approval for the treatment of patients with chronic lymphocytic leukemia, the most common form of leukemia in the United States.

Indolent NHL, a subset of non-Hodgkin's lymphoma, is a slow growing but serious cancer of the lymphatic system that is not curable with currently available treatments. Patients with indolent NHL are prone to multiple relapses after initial therapy. According to the National Cancer Institute, an estimated 30,000 people in the United States will be diagnosed this year with indolent NHL.

"Because most patients with indolent non-Hodgkin's lymphoma eventually become resistant to existing treatments, new treatment options like Treanda are needed to improve patient outcome," stated Dr. Bruce Cheson, Professor of Medicine at Georgetown University Hospital, Washington, D.C. and Treanda clinical investigator. "The Treanda pivotal trial shows that it is an effective and well-tolerated chemotherapy that offers a delay in disease progression for more than nine months."

According to Dr. Lesley Russell, Executive Vice President and Chief Medical Officer, Cephalon, "We are excited about this second FDA approval for Treanda in 2008. This approval of Treanda for indolent non-Hodgkin's lymphoma is a significant milestone in our development of a diverse oncology portfolio of products that improve patient outcomes."

The FDA approval is supported by a pivotal trial of 100 patients with indolent B-cell NHL who had progressed during or within six months of treatment with a regimen that included rituximab. The pivotal study demonstrated that patients had a high response rate to treatment with Treanda, and these responses to the treatment were durable. The results from the pivotal study showed that treatment with Treanda as a single agent resulted in an overall response rate of 74 percent, which means that after treatment, the cancer diminished or disappeared in approximately three out of four patients. Additionally, patient response to treatment in the pivotal study lasted a median of 9.2 months and patients remained alive and their disease did not progress for a median of 9.3 months.

The safety of Treanda is also supported by a secondary monotherapy study. In the pivotal and secondary studies for Treanda in indolent NHL, the most common non-hematologic adverse reactions (frequency > 15%) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decrease, dyspnea, rash and stomatitis. The most common hematologic abnormalities (frequency >15%) are lymphopenia, leukopenia, anemia, thrombocytopenia and neutropenia.

In addition to its proven efficacy and tolerable side effect profile, Treanda has a convenient dosing schedule as a treatment for indolent NHL. An intravenous infusion takes 60 minutes and can be administered in an outpatient setting, reducing the time it takes for patients to be treated. The recommended dose for indolent NHL is 120 mg/m2 administered on days one and two of a 21-day cycle, for up to eight cycles.

About Treanda

Treanda is a novel treatment with a unique chemical structure that is synthesized to combine an alkylating group and a purine-like benzimidazole component. Though the exact mechanism of action of Treanda remains unknown, Treanda may act in two distinct ways to kill cancer cells. Preclinical studies suggest that Treanda may lead to cell death by a process known as apoptosis (programmed cell death) as well as by an alternate cell death pathway which disrupts normal cell division known as mitotic catastrophe (a non-apoptotic pathway).

Cephalon holds exclusive rights to market and develop Treanda in the United States. Treanda is licensed from Astellas Deutschland GmbH. Bendamustine HCl, the active ingredient in Treanda, is marketed in Germany by Astellas' licensee, Mundipharma International Corporation Limited. In Germany, bendamustine 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 select Asia Pacific Rim countries.

About Cephalon Oncology

Cephalon, a leading biopharmaceutical company, is building a diversified portfolio of oncology products that represents a comprehensive approach to extend and enhance the lives of patients with cancer. 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(R) (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 injection, Treanda, AMRIX (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 approval of any current or future filings for regulatory approval of Treanda or other Cephalon 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.

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