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SymBio Pharmaceuticals Limited
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Cephalon Receives FDA Approval for TREANDA® to Treat Patients with Relapsed Indolent Non-Hodgkin's Lymphoma

TREANDA® Receives Second Indication this Year;

Data Demonstrate High, Durable Response Rates for Patients with indolent NHL Who Have Progressed Following a Rituximab-Containing Regimen

FRAZER, Pa., Oct. 31 -- Cephalon, Inc., (Nasdaq: CEPH) 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/㎡ administered on days one and two of a 21-day cycle, for up to eight cycles.

[About Bendamustine hydrochloride]

Cephalon holds exclusive rights to market and develop TREANDA® in the United States. TREANDA® is licensed from Astellas Deutschland GmbH. SymBio Pharmaceuticals Ltd holds exclusive rights to develop and market bendamustine HCl, the active ingredient in TREANDA® in Japan, China, Korea, Taiwan and Singapore and is now conducting a Phase II clinical trial of SyB L-0501 at 18 facilities, with patients who have relapsed/refractory indolent non-Hodgkin's lymphoma. Bendamustine HCl 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.

[Company Profile]
SymBio Pharmaceuticals Ltd. was established in March 2005 by Fuminori Yoshida, who previously served as both Corporate VP of Amgen Ltd. and President of Amgen Japan (currently Takeda Bio Development Center Limited). The company's underlying corporate philosophy is "delivering hope to patients in need," and the company aims to address the unmet medical needs of patients in Japan and other Asia Pacific regions by cultivating a mutually beneficial or symbiotic relationship among physicians, scientists, investors, government, and patients in the healthcare industry.

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