



March 26, 2007

Enzastaurin Granted Orphan Drug Status for Treatment of Diffuse Large B-Cell Lymphoma (DLBCL)

Oral Agent Designed to Address High Incidence of Relapse in DLBCL Population

INDIANAPOLIS, March 26, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company announced today that the European Medicines Agency (EMA) has granted enzastaurin, an investigational, multi-targeted, oral, cancer agent, orphan drug designation for the treatment of diffuse large B-cell lymphoma (DLBCL). Although rare, DLBCL is the most common sub-type of non-Hodgkin's lymphoma (NHL) of which approximately 50% of high-risk patients (high-risk is defined as having an International Prognostic Index score of 3-5) relapse within three years after receiving first line therapy. (1) An International Prognostic Index score (IPI) is a criteria determined by a patient's oncologist.

Enrollment into a Phase III clinical trial studying enzastaurin is currently underway. The PRELUDE (Preventing Relapse in Lymphoma Using Daily Enzastaurin) trial is a randomized, placebo controlled study in DLBCL patients at high risk for relapse who have achieved remission following first-line therapy. Specifically, enzastaurin is being investigated as a maintenance therapy to prevent disease relapse. The study will compare the efficacy, safety and tolerability of enzastaurin, taken orally for up to three years, versus placebo. The study is expected to enroll 459 patients across 100 sites worldwide. The primary endpoint of the study will be overall disease-free survival. More details on the study design, inclusion criteria and how to enroll are available at www.lillytrials.com or by visiting www.clinicaltrials.gov.

"In recent years, there has been progress in improving first-line therapies that help more patients achieve remission. However, our objective with enzastaurin is to develop an agent that may fill this important therapeutic need -- the ability to keep DLBCL patients in remission," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Eli Lilly and Company.

Enzastaurin

Enzastaurin is an oral, serine threonine kinase inhibitor which selectively targets the PKCBeta and PI3/AKTsignaling pathways. By blocking these key pathways frequently over-expressed in a wide variety of cancers, enzastaurin suppresses tumor cell proliferation, induces tumor cell death and inhibits tumor-induced angiogenesis. Treatment has been well tolerated with minimal drug-related toxicity. Enzastaurin administration is associated with fatigue, diarrhea, nausea, decreased platelets, cough, vomiting, transaminase elevation, dyspnea, peripheral edema, and dizziness. Further testing in Phase III versus a placebo will provide us with a more complete look at the side effect profile for enzastaurin. In addition to DLBCL, enzastaurin is also being studied in other tumor types including breast, colon, lung, ovarian and prostate cancers.

Non-Hodgkin's Lymphoma and Diffuse Large B-cell Lymphoma

Non-Hodgkin's lymphoma is the most common cancer of the lymphatic system, the body's defense mechanism against infection and disease. Once considered rare, non-Hodgkin's lymphoma rates have increased 83 percent in the past 25 years. NHL is now considered the fifth most common of all cancers, with more than 56,000 new diagnoses made in the United States each year and 46,000 new cases each year in the European Union.

Diffuse large B-cell lymphoma (DLBCL) describes the appearance of the malignant B-cells in the lymphoma and it is the most frequently occurring histologic subtype in adults, constituting approximately 31% of all new diagnoses (Armitage and Weisenburger 1998). The vast majority of relapses occur in the first 2 years after therapy (Cabanillas et al. 1992). Life expectancy of untreated patients with DLBCL is very short.

Orphan Medical Product Designation in the European Union

Orphan medicinal products are for diagnosing, preventing or treating life- threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union.

About Lilly Oncology, a division of Eli Lilly and Company

For more than four decades, Lilly Oncology has been collaborating with cancer researchers to deliver innovative treatment choices and valuable programs to patients and physicians worldwide. Inspired by the courageous patients living with cancer, Lilly Oncology is providing treatments that are considered global standards of care and developing a broad portfolio of novel targeted therapies to accelerate the pace and progress of cancer care.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers -- through medicines and information - for some of the world's most urgent medical needs.

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This press release contains forward-looking statements about the potential of the investigational compound enzastaurin (LY317615) and reflects Lilly's current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the product will receive regulatory approvals, or that the regulatory approval will be for the indication(s) anticipated by the company. There is also no guarantee that the product will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

(1) Shen, Laurie H and col. 2007. The Revised International Prognostic Index (R-IPI) is a better predictor of outcome than the standard IP for patients with diffuse large B cell Lymphoma treated with RCHOP. Blood 109 (N5):1857, 1861.

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