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Lilly Launches Phase III Trial of Once-Daily, Targeted Oral Cancer Agent

Late-stage trial in non-Hodgkin's lymphoma currently enrolling patients

INDIANAPOLIS, May 31, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- For the second time in as many months, Eli Lilly and Company has announced the initiation of a Phase III clinical trial studying enzastaurin, an investigational, multi-targeted, oral, cancer agent. This trial will investigate enzastaurin's potential in treating patients with non-Hodgkin's lymphoma (NHL), the most common cancer of the lymphatic system, which acts to defend the body against disease. Specifically, enzastaurin will be evaluated as a maintenance therapy in patients with diffuse large B-cell lymphoma who have achieved remission following first-line therapy. Diffuse large B-cell lymphoma (DLBCL) is the most common form of NHL and the goal of maintenance therapy is to prevent relapse. In March, Lilly announced the first Phase III trial for enzastaurin in glioblastoma, a common type of brain cancer. Phase II trial results for enzastaurin in glioblastoma and non-Hodgkin's lymphoma were presented at last year's American Society of Clinical Oncology and American Society of Hematology annual meetings, respectively.

"The incidence of non-Hodgkin's lymphoma has been increasing rapidly over the past 25 years," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Eli Lilly and Company. "In recent years, there has been much progress in developing therapies that get more patients into remission. However, our objective with enzastaurin is to develop an agent with the ability to keep NHL patients in remission. Early clinical studies of enzastaurin in NHL have been promising and we are excited about continuing our investigation in this trial."

The enzastaurin non-Hodgkin's lymphoma Phase III trial (PRELUDE - Preventing Relapse in Lymphoma Using Daily Enzastaurin) is a randomized, placebo controlled study of patients in their first remission from DLBCL. The study will compare the efficacy, safety and tolerability of enzastaurin, taken orally for up to three years, versus placebo. A steering committee will oversee this study, which is planned to enroll 459 patients across 100 sites worldwide. The primary endpoint of this study will be overall disease-free survival. Additionally, Lilly will be assessing any biomarkers relevant to enzastaurin as a basis for correlating patient response to clinical trial outcomes. Following the appropriate administrative steps, more details on the study design and information on global recruitment sites will be available at www.clinicaltrials.gov, www.lillytrials.com or by calling 1-877-CTLilly (1-877-285-4559).

Enzastaurin is an oral serine-threonine kinase inhibitor that is designed to suppress tumor growth through a distinct mechanism of action. Preclinical data suggest it may attack the tumor in three ways: by reducing the cell's ability to divide (cell proliferation), increasing the natural death of the tumor cells (apoptosis), and inhibiting tumor-induced blood supply (angiogenesis). Data have suggested enzastaurin inhibits signaling through the PKC-beta and PI3K/AKT pathways. These pathways have been shown to be activated in a wide variety of cancers. In addition to non-Hodgkin's lymphoma, enzastaurin is also being studied in other tumor types, including glioblastoma, colorectal cancer, non-small cell lung cancer, pancreatic cancer, and mantle cell lymphoma.

Non-Hodgkin's 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.

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. To learn more about Lilly's commitment to cancer, please visit www.LillyOncology.com.

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 filing with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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