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Investigational Targeted Therapy May Offer Progress for Non-Hodgkin's Lymphoma Patients

INDIANAPOLIS, Dec 10, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Data presented today offer evidence that an investigational targeted therapy may be useful in treating patients with the most common form of non-Hodgkin's lymphoma (NHL).

The five-year survival rate of U.S. patients with NHL is only 59 percent with standard therapies, according to the Lymphoma Research Foundation. Diffuse large B-cell lymphoma (DLBCL) is the most frequent form of NHL (1). Conventional therapies improve outcomes for some patients, but new treatment options are always needed.

Phase II data presented today at the American Society of Hematology (ASH) 47th Annual Meeting and Exposition in Atlanta, Georgia, showed enzastaurin HCl, an investigational compound from Lilly Oncology, slowed the progression of DLBCL in several patients pretreated with chemotherapy.

"The use of enzastaurin in relapsed diffuse large B-cell lymphoma is important for two reasons," said Margaret A. Shipp, M.D. director of Dana-Farber/Harvard Cancer Center's lymphoma program and the senior investigator in the clinical trial. "One, it represents a rational inhibitor of an identified target and, two, several patients with aggressive chemo-insensitive disease have had prolonged responses to this single, oral agent."

Enzastaurin inhibits the PKC-Beta and AKT/P13 pathways. This protein, PKC-Beta, stimulates cell growth. Based on scientific rationale from initial multicenter studies led by Shipp and from independent confirmatory studies by other investigators, an overexpression of PKC-Beta was identified as being linked to poor outcomes for patients with DLBCL. Enzastaurin, created to target PKC-Beta, was seen as a worthy candidate for further study in these patients.

In addition, preclinical data indicate that enzastaurin may have additional effects on cutting off the tumor's blood supply (anti-angiogenesis), increasing the natural death of tumor cells (apoptosis) and reducing the cell's ability to reproduce (cell proliferation).

The Phase II multicenter clinical trial evaluated 55 DLBCL patients previously treated with a median of two other therapies, but like many patients with this aggressive cancer, they experienced relapses. Data, presented at ASH by Michael J. Robertson, director of Indiana University Cancer Center's lymphoma program, showed 22 percent (12 of 55) of study participants treated with enzastaurin were free of disease progression for two months. A quarter of those patients remained progression free with continued responses of 1.5 years to more than three years in duration.

Overall, enzastaurin was well tolerated in this patient population and clinical results show that patients treated with enzastaurin experienced minimal side effects. Seven reports of grade 3 side effects were reported in this trial which included fatigue, thrombocytopenia (a low level of platelets in the blood), headache, motor neuropathy (pain, numbness and weak muscles), and edema (swelling caused by excess fluid), with only one patient experiencing grade 4 hypomagnesemia (low levels of magnesium in the blood).

"We at Lilly are excited by the potential for enzastaurin in the treatment of patients with recurrent diffuse large B-cell lymphoma," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Eli Lilly and Company. "We're also evaluating enzastaurin for patients with glioblastoma, a form of primary brain cancer with few adequate treatments. Our commitment to continuous innovation in cancer care has resulted in enduring therapies such as Gemzar(R) and Alimta(R), which are already helping patients with pancreatic, bladder, breast, mesothelioma and lung cancers."

Today's data support continued development of enzastaurin, and Lilly will soon begin enrolling patients in a Phase III registration trial. Researchers will be evaluating enzastaurin to determine if it can delay relapse in patients who have already undergone treatment for DLBCL and have achieved remission following the standard of care. In addition to non-Hodgkin's lymphoma and glioblastoma, enzastaurin will be evaluated in other tumor areas such as colon cancer, non-small cell lung cancer and mantle cell lymphoma.

Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma is the most common cancer of the lymphatic system. Since the early 1970s, U.S. incidence rates for non-Hodgkin's lymphoma have nearly doubled. Over the 25-year period between 1973 and 1998, new cases of NHL seen each year escalated almost 83 percent, among the highest increases of any cancer. Of the nearly 500,000 Americans with lymphoma, 332,000 have this form. In 2005, approximately 56,390 new cases of NHL will be diagnosed and 19,200 Americans will die from the disease (2).

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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.

(1) Lymphoma Research Foundation, "Learning About Lymphoma," Lymphoma Research Foundation, February 2005, <http://www.lymphoma.org> (November 9, 2005)

(2) Lymphoma Research Foundation, "Learning About Lymphoma," Lymphoma Research Foundation, February 2005, <http://www.lymphoma.org> (November 9, 2005)

Gemzar(R) (gemcitabine, Eli Lilly and Company)
Alimta(R) (pemetrexed, Eli Lilly and Company)

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