May 10, 2013

Lilly Announces Enzastaurin Phase III Study Did Not Meet Primary Endpoint in Diffuse Large B-Cell Lymphoma

INDIANAPOLIS, May 10, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today Phase III clinical trial results from enzastaurin's PRELUDE study, which explored the molecule as a monotherapy in the prevention of relapse in patients with diffuse large B-cell lymphoma (DLBCL). The study failed to show a statistically significant increase compared to placebo in disease-free survival in patients at high risk of relapse following rituximab-based chemotherapy. There were no new safety findings, and the safety data were consistent with previously disclosed studies.

"We are disappointed in the results that we're announcing today," said Richard Gaynor, M.D., vice president, product development and medical affairs for Lilly Oncology. "However, our oncology pipeline is still one of the most robust across the industry containing more than 20 molecules, including two Phase III molecules in five different tumor types."

Lilly plans to present data from this study at an upcoming scientific meeting.

Lilly will stop development of enzastaurin, which is expected to result in a second-quarter charge to R&D expense of approximately $30 million. The company's previously-issued financial guidance for 2013 remains unchanged.

About the Study
Patients enrolled in PRELUDE had histologically confirmed DLBCL with an International Prognostic Index (IPI) score of three to five at diagnosis. The IPI is a simple, clinical tool that is used to predict survival outcomes for patients with DLBCL. Patients enrolled also achieved a complete response or complete response-unconfirmed to cyclophosphamide, doxorubicin, vincristine, and prednisone, plus rituximab (R-CHOP) therapy. Patients were randomized in a 2:1 fashion to receive enzastaurin or placebo.

Treatment continued until patients developed progression of disease, unacceptable adverse events, or completed three years of therapy.

About Enzastaurin
Enzastaurin (LY317615 HCl) is an investigational oral small molecule, serine/threonine kinase inhibitor of the PKC beta and AKT pathways. [1],[2]

About Diffuse Large B-cell Lymphoma
Non-Hodgkin's lymphomas (NHL) are cancers of the body's lymphatic system consisting of clonal proliferation of immune cells. Non-Hodgkin's lymphomas constitute a heterogeneous group of malignant tumors with a wide variety of histologic appearances, clinical behaviors, and prognoses. (Armitage 1993). DLBCL is a sub-type of NHL.

About Lilly's Pipeline
Lilly currently has a number of unique potential medicines in its Phase III clinical development pipeline, representing a variety of therapeutic areas including diabetes, cancer, neuroscience, autoimmunity and cardiovascular. To learn more about the molecules in Lilly's clinical development pipeline, please visit Lilly's interactive pipeline website available at www.lilly.com/pipeline.

About Lilly Oncology
For more than four decades, Lilly Oncology, a division of Eli Lilly and Company, has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Because no two cancer patients are alike, Lilly Oncology is committed to developing novel treatment approaches. 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 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. Additional information about Lilly is available at www.lilly.com.

P-LLY

This press release contains forward-looking statements about the potential of enzastaurin as a treatment of DLBCL and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future studies will be positive or that enzastaurin will receive regulatory approvals or 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.

Refer to:
Keri S. McGrath, Lilly Oncology
317-277-3768 (office)
317-370-8394 (mobile)
Email: mcgrath_happe_keri_s@lilly.com

[1] Graff JR, et al. Cancer Res. 2005; 65:7462-7469
[2] Brautigam K, et al. Transl Oncol. 2009; 2; 164-173

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company