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Data Monitoring Committee Recommends Closing Enrollment in Recurrent Glioblastoma Study

- Other Enzastaurin Trials Unaffected -

INDIANAPOLIS, Dec 21, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- After reviewing data gathered to date, as part of a planned interim analysis, an External Data Monitoring Committee (DMC) has recommended that the STEERING trial (Study Evaluating Enzastaurin in Recurrent Glioblastoma) be closed for enrollment. The global Phase III study was evaluating enzastaurin for the treatment of an aggressive and recurrent form of brain cancer.

Results of this planned interim analysis suggested that enzastaurin would not meet the primary endpoint of improvement in progression-free survival over an existing chemotherapy in this particular study. Lilly accepted the DMC recommendation and immediately contacted all STEERING study investigators to inform them of the decision and to provide them all available information to manage patients.

"We are disappointed for patients suffering from recurrent glioblastoma, but we remain confident and committed to the development of enzastaurin," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Eli Lilly and Company. "Recurrent glioblastoma is a rare and difficult to treat tumor and patients and their families are seeking innovative treatment options. Given the independently validated response rate of 22-percent in a phase II trial, we plan to thoroughly review the data from this interim analysis and apply the insights learned to the glioblastoma program. Based on preclinical and clinical evidence, the company also remains fully committed to the continued development of enzastaurin."

Enzastaurin is being evaluated in a Phase III trial (currently enrolling patients) as a maintenance therapy for the treatment of non-Hodgkin's lymphoma as well as being evaluated in several phase II studies across a variety of more common tumor types including: breast, colon, lung, ovarian and prostate cancers. These additional trials are unaffected by the DMC recommendation.

Enzastaurin

Enzastaurin is a potent multi-kinase inhibitor which targets selectively the PKC β and PI3/AKT signaling 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. As further evidence to the rare and unmet medical need of recurrent glioblastoma, enzastaurin was granted orphan drug designation by the European Agency for the Evaluation of Medicinal Products (EMA) and by the U.S. Food and Drug Administration's Office of Orphan Products Development for the treatment of glioblastoma.

Background on STEERING Trial

The STEERING trial (Study Evaluating Enzastaurin in Recurrent Glioblastoma) is a randomized, open label registration study in recurrent glioblastoma multiforme (GBM) comparing the efficacy and safety of enzastaurin, taken orally, versus CeeNU® (lomustine[CCNU]), a chemotherapy used to treat this disease. The primary endpoint is improvement in progression-free survival.

Glioblastoma

Glioblastoma is the most aggressive and malignant form of glioma, a type of primary brain cancer. In the early stages, glioblastoma tumors often grow quickly and without symptoms, becoming quite large before signs of altered brain function arise. Surgery is generally the first line of treatment, followed by radiation and/or chemotherapy. Although primary treatment is often successful in temporarily stopping the progression of the tumor, glioblastomas almost always recur and survival rates remain low.

Data Monitoring Committee

A Data Monitoring Committee (DMC) is an independent body consisting of physicians and statisticians. Their responsibility is to

review interim analysis data from clinical trials and make a decision on whether the trial is still set up correctly or needs any modifications.

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. Additional information about Lilly is available at www.lilly.com.

P-LLY

This press release contains forward-looking statements about the potential of the investigational compound enzastaurin 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.

CeeNU® (lomustine [CCNU], Bristol Myers Squibb)

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SOURCE Eli Lilly and Company

Christine Van Marter of Eli Lilly and Company, +1-317-651-1473, vanmarterch@lilly.com

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