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Lilly Announces Phase II Results for ALIMTA(R) in First-Line Metastatic Breast Cancer Trial

Study Also Explored Biomarkers' Correlation to Drug Efficacy

ATLANTA, June 4, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- At the 42nd American Society of Clinical Oncology (ASCO) annual meeting in Atlanta, Ga., Eli Lilly and Company announced results of a Phase II trial evaluating its leading thoracic cancer drug, ALIMTA(R) (pemetrexed) in first-line metastatic breast cancer. The study also detailed exploratory pharmacogenomic analyses, to potentially identify the presence of specific biomarkers for Alimta. Lilly's study is among the first bodies of research evaluating the potential use of biomarkers with chemotherapy agents.

The Phase II study was a randomized, double-blind trial of 92 patients with locally advanced or metastatic breast cancer (MBC). The two sets of patient groups were given two different doses of Alimta.

The study concluded that since efficacy and safety for both doses were similar, the lower dose (600 mg/m squared) is suitable for further study. In addition, exploratory biomarker analysis suggests an efficacy correlation for FFGS (folypolyglutamate synthase) and TP (thymidine phosphorylase).

"We are encouraged by these results," said Allen Melemed, M.D., Lilly associate medical director and a study author. "And while it's too soon to be conclusive, it does seem like we're heading in the right direction. Our hope is to be able to offer patients and their doctors more choices, and to one day help them know with more certainty, which ones work for them."

Lilly is considering plans for a Phase III trial, as well as further evaluation of the biomarkers that were explored.

More on the Study

The trial enrolled women with a histologic/cytologic diagnosis of breast cancer, and evidence of locally recurrent disease or distant metastasis, not amenable to local therapy. Patients received Alimta (Arm A: 600 mg/m squared; Arm B: 900mg/m squared) on a 21-day cycle, with a median of six cycles delivered. All patients received folic acid and vitamin B12 supplementation. Forty-seven patients, aged 33-81 years (with a median age of 57), enrolled in Arm A and 45 in Arm B.

Arm A and B had response rates of 17 percent and 15 percent, median progression-free survival times of 4.2 and 4.1 months, and median time-to- tumor progression (TtTP) of 4.2 and 4.6 months, respectively. Toxicity was mild in both arms (grade 3/4); neutropenia less than 20 percent; leucopenia less than 9 percent). (Both neutropenia and leucopenia are related to lowered white blood cell count.) Non-hematologic side effects were mild and similar to those commonly experienced when Alimta is used as monotherapy, e.g., disorders of the blood and lymphatic system, gastrointestinal disorders, fatigue, rash and desquamation.

Primary tumor samples from 49 patients were assessed for gene expressions. Two markers, FPGS and TP, showed the most conclusive results. Best response rates and median TtTP for high vs. low FPGS expression subgroups were: 37.5 percent vs. 10 percent, and 8.57 vs. 2.99 months. The results for TP were 27.6 percent vs. 6.2 percent, and 5.39 vs. 1.94 months.

About ALIMTA(R)

Alimta was first approved by the U.S. Food and Drug Administration in 2004 for second-line treatment of non-small cell lung cancer, and for malignant pleural mesothelioma. In the two years since its first approval for marketing, Alimta has been approved in 71 countries for either NSCLC or mesothelioma and has become the leader for these indications in most markets. Delivered via a 10-minute infusion that shows virtually no hair loss, Alimta is an antifolate, which interferes with a crucial process that allows cancer cells to reproduce and spread.

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.

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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ALIMTA(R) (pemetrexed), Lilly

This press release contains forward-looking statements about the potential of Alimta for the treatment of metastatic breast cancer 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 the product will receive regulatory approval for a further indication, or that it will continue 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.

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