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Lilly Breast Cancer Studies Explore Potential Role of Pharmacogenomics in Customizing Chemotherapy

ATLANTA, June 3, 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, a leader in thoracic cancer, unveiled two breast cancer studies involving pharmacogenomics and its chemotherapies GEMZAR(R) (gemcitabine HCl) and ALIMTA(R) (pemetrexed). They are among the early trials involving pharmacogenomics (the study of gene expression patterns) in breast cancer treatment.

Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Lilly said, "While these are preliminary trial results, the hope is that in the future, treatment-predictive pharmacogenomics may lead to highly tailored treatments that offer optimum patient outcomes."

While breast cancer has been the focus of much research and attention over the years, it is only in recent times that this cancer has been recognized as not one but many diseases, according to Vered Stearns, M.D., assistant professor of oncology, Johns Hopkins School of Medicine and an ASCO presenter on the subject of breast cancer and pharmacogenomics.

Stearns said, "This new outlook on breast cancer will move treatment from the 'one-size-fits-all' to the personalized medicine approach."

"Right now, we treat cancer based on stage, age, other diseases, etc., as opposed to what the actual cancer of that woman looks like," said Stearns, adding, "And we tend to over-treat because we're worried about the cancer coming back. Pharmacogenomics can help analyze tumors' specific genetic make- up to potentially guide cancer treatment decisions, thereby avoiding unnecessary toxicity, and leading to better patient outcomes."

According to Gaynor, chemotherapies, which remain the foundational therapies of choice, may experience a new resurgence if pharmacogenomics can be employed in hopes of maximizing treatment success.

This "right patient, right drug, right time" philosophy is what guides Lilly Oncology. "Cancer is personal -- it affects different people differently, from a biological, physiological, and psychological perspective," said Gaynor. "And Lilly is responding by working to personalize and optimize its prevention and treatment, with innovative research and solutions including chemotherapies, targeted agents and pharmacogenomics."

Expression profiles can predict chemotherapy response in breast cancer patients

In a correlative study on a combined analysis of approximately 90 women receiving neoadjuvant (pre-surgical) chemotherapy, researchers sought to identify gene expression profiles/biomarkers that predict patients' response to chemotherapy. They also tried to determine whether these biomarkers were drug-specific.

Scientists from the University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center and Lilly Research Laboratories in Indianapolis, Ind. evaluated two groups of locally advanced breast cancer patients receiving chemotherapy. DNA microarray analysis (a technologically advanced way to perform quicker analyses of many genes in a single experiment) was performed on pre-treatment core biopsies from the patients. They then treated the first group of patients (L9819) with four cycles of doxorubicin + cyclophospharmide (AC), followed by four cycles of paclitaxel (Taxol(R)) or paclitaxel + trastuzumab (Herceptin(R)). The second group of patients (S329) received four cycles of Gemzar + doxorubicin followed by four cycles of Gemzar + cisplatin. Clinical response was based on RECIST criteria.

Successful microarrays were obtained on 45 of the L9819 group and 46 of the S329 group, and separate analyses on each dataset identified gene expression patterns that predicted with 75-80 percent accuracy clinical response on those patients that completed all eight cycles of chemotherapy. Comparisons of both L9819 and S329 predictors indicated that the study may provide the means to predict response related to both general and drug- specific chemotherapy, in this case Gemzar. (For data on adverse effects, refer to the institutional, clinical trial for which this trial ran as a correlative study: LCCC 9818: A Nonrandomized Phase II Study Of Multimodality Therapy For Stage IIB, IIIA/B, Or Initially Presenting Stage IV Breast Cancer With 4 Cycles Of AC Followed By 12 Weeks Of Single Agent Taxol(R) With Or Without Herceptin(R) Followed By Local Therapy Followed By Weekly Herceptin(R) Or No Additional Therapy.)

Phase II Study of Alimta as first-line therapy for advanced breast cancer

Another Lilly study compared two doses of Alimta in advanced breast cancer, and attempted to identify potential biomarkers. The main objective of the study was to access response rate on the two arms, and conduct exploratory biomarker analysis. Further analysis of this study will be released at ASCO on Sunday, June 4, 2006 at 2:00 pm EDT.

About Gemzar(R)

Gemzar, celebrating its 10th anniversary in the US, is approved in more than 90 countries and has been prescribed to more than 1.3 million patients worldwide. It is the foundation for many drug combinations, and the focus of much clinical research. Gemzar interferes with the processes of DNA production, preventing cancer cell replication, and therefore, stopping or slowing tumor growth. Possessing broad activity across numerous tumor types, Gemzar is the worldwide standard of care for pancreatic cancer and is also a standard of care in many parts of the world for non-small cell lung, metastatic breast and bladder cancers. Gemzar is also approved in a number of European countries for recurrent ovarian cancer, and in Mexico for metastatic cervical cancer.

About ALIMTA(R)

Alimta was first approved by the US Food and Drug Administration in 2004 for second-line treatment of non-small cell lung cancer (NSCLC), 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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Gemzar(R) (gemcitabine HCl), Lilly
ALIMTA(R) (pemetrexed), Lilly
Taxol(R) (paclitaxel), Bristol-Myers Squibb
Herceptin(R) (trastuzumab), Genentech
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This press release contains forward-looking statements about the potential of Gemzar and ALIMTA for the treatment of 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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