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New Study Results Demonstrate Clinical Effectiveness of Gemzar(R)-Based Combination Therapy for Advanced Breast Cancer

INDIANAPOLIS, May 16, 2005 /PRNewswire-FirstCall via COMTEX/ -- New data from a Phase III clinical trial(1) show that Eli Lilly and Company's (LLY) Gemzar(R) (gemcitabine, HCl) in combination with Taxotere(R) (docetaxel) demonstrated similar efficacy, but with an improved safety profile, when compared to a regimen of Xeloda(R) (capecitabine) and docetaxel in the treatment of metastatic breast cancer.

The study, presented today at the 41st annual meeting of the American Society of Clinical Oncology (ASCO), compared the two combinations as first- or second-line treatment in patients with metastatic breast cancer. The study further demonstrates Gemzar's ability to be combined with other agents in providing patients with the benefit of survival, while maintaining a manageable level of side effects. Gemzar in combination with Taxol(R) (paclitaxel) is approved for use in the U.S., Europe and more than 60 countries for the treatment of metastatic breast cancer.

Patients receiving the Gemzar-based combination had the same progression- free survival time (the length of time during and after treatment that the cancer does not grow) and tumor response rate (tumor shrinkage) as patients receiving the capecitabine-based combination. Patients administered the Gemzar combination also experienced significantly fewer toxic side effects, such as mucositis (an inflammation of the gastrointestinal lining resulting in painful sores in the mouth and throat), diarrhea and hand-foot syndrome (a drug-related skin condition that results in redness, tenderness, peeling and numbness of the palms and soles).

"Treatment-related side effects can be severely debilitating for women with metastatic breast cancer and have a tremendous impact on their quality of life," said Stephen Chan, M.D., Consultant Oncologist, Nottingham City Hospital, United Kingdom, and primary investigator of the study. "The combination of efficacy and improved tolerability seen in this study with Gemzar/docetaxel suggests that we've taken an important step forward where we can treat the cancer while helping women live their everyday lives more comfortably and with less risk of side effects."

Study Highlights

This 16-month study evaluated 302 patients with pre-treated metastatic breast cancer who were randomized and treated with either Gemzar/docetaxel (n=152) or capecitabine/docetaxel (n=150) combination therapy. The primary endpoint of this study was progression-free survival. Secondary endpoints were overall response rate, time to treatment failure, overall survival, toxicity and quality of life.

Patients in the Gemzar/docetaxel arm were treated with 1000 mg/m2 of Gemzar combined with 75 mg/m2 of docetaxel, and patients in the capecitabine/docetaxel arm were treated with 1250 mg/m2 of capecitabine combined with 75 mg/m2 of docetaxel. Patients in the Gemzar/docetaxel group and capecitabine/docetaxel group received 875 and 758 cycles of therapy, respectively.

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*  Patients receiving Gemzar/docetaxel had the same median progression-
       free survival time and overall tumor response rate as patients who
       received capecitabine/docetaxel
    *  The Gemzar/docetaxel combination resulted in fewer non-hematologic
       toxic side effects compared to capecitabine/docetaxel
       --  Grade 3/4 mucositis - 4 percent vs. 17 percent
       --  Grade 3/4 diarrhea - 8 percent vs. 18 percent
       --  Grade 3/4 hand-foot syndrome - 0 percent vs. 26 percent
    *  Gemzar/docetaxel resulted in a slightly higher percentage of
       hematologic side effects compared to capecitabine/docetaxel with the
       exception of febrile neutropenia (a fever accompanied by a significant
       reduction in white blood cell count, leading to greater likelihood of
       developing an infection and increased need for hospitalization)
       --  Grade 3/4 neutropenia (a lowering of the white blood cell count
           that can cause infections and fever, thus requiring
           hospitalization) - 85 percent vs. 82 percent
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- -- Grade 3/4 leukopenia (an abnormal decrease in the number of white blood cells) - 80 percent vs. 66 percent
- -- Grade 3/4 thrombocytopenia (a decrease in the number of platelets in the blood, resulting in the potential for increased bleeding and decreased ability for clotting) - 10 percent vs. 3 percent
- -- Grade 3/4 febrile neutropenia - 8 percent vs. 13 percent
- -- Grade 3/4 anemia (a decrease in red blood cell count resulting in insufficient oxygen to tissues and organs) - 7 percent vs. 3 percent

* There was a lower discontinuation rate due to adverse events in the Gemzar/docetaxel group compared to the capecitabine/docetaxel group (13 percent vs. 28 percent, respectively) - more patients stopped their therapy on the capecitabine/docetaxel arm due to a higher occurrence of adverse events.
* There were two toxic deaths in the trial, both occurring in the capecitabine/docetaxel group of patients.

According to the World Health Organization, more than one million people worldwide will be diagnosed with breast cancer this year, making it the most common cancer among women(2).

"Gemzar has been shown to have significant therapeutic value on its own as a cancer-fighter and as a highly combinable agent. We are extremely pleased that Gemzar-based combination therapy continues to deliver in the fight against breast cancer," said Allen Melemed, M.D., medical advisor, Eli Lilly and Company. "Women and their physicians deserve our total and ceaseless commitment to finding new options in breast cancer, and we will continue to look for ways to improve the treatment picture."

Gemzar

Gemzar is one of the most widely studied treatments in the history of chemotherapy agents, and has been approved for use in more than 90 countries worldwide. It is the worldwide standard for care of pancreatic cancer and in many parts of the world for non-small cell lung, bladder and breast cancers. Gemzar is approved in more than 75 countries as a single agent for the treatment of locally advanced or metastatic pancreatic cancer. It is also approved, in combination with Taxol(R) (paclitaxel), in more than 60 countries for the treatment of metastatic breast cancer. In most European countries, Gemzar is approved as a single agent or in combination with cisplatin for the treatment of advanced non-small cell lung cancer. Gemzar, in combination with carboplatin, is approved in several European markets for the treatment of recurrent epithelial ovarian cancer. Most recently, Gemzar was approved in Mexico for cervical cancer, making it the first approval for this disease. Gemzar is a nucleoside analogue that interferes with the process of DNA production; thereby preventing cancer cells from replicating and thus slows or stops tumor growth.

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This press release contains forward-looking statements about Gemzar in combination with Taxotere 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 commercialization. There is no guarantee that the product will receive additional regulatory approvals and there is also no guarantee that the product will continue 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.

Gemzar(R) (gemcitabine HCl, Lilly)
Taxol(R) (paclitaxel, Bristol-Myers Squibb)
Xeloda(R) (capecitabine, Roche)
Taxotere(R) (docetaxel, Sanofi-Aventis)

(1) Gemcitabine plus docetaxel versus capecitabine plus docetaxel for anthracycline-pretreated metastatic breast cancer patients: Results of a European phase III study; Chan S, Romieu G, Huober J, Delozier T, Tubiana- Hulin M, Lluch A, Schneeweiss A, Llombart A, Carrasco E, Fumoleau P

(2) "Global cancer rates could increase by 50% to 15 million by 2020." World Health Organization 3 April 2003; Accessed 26 April 2005 http://www.who.int/mediacentre/news/releases/2003/pr27/en/

	Gemzar/docetaxel (n=152)	Xeloda/docetaxel (n=150)
Median Progression-Free Survival Time	35 weeks	35 weeks
Overall Tumor Response Rate	32 percent	32 percent
Grade 3/4 Mucositis	4 percent	17 percent
Grade 3/4 Diarrhea	8 percent	18 percent
Grade 3/4 Hand-Foot Syndrome	0 percent	26 percent
Grade 3/4 Neutropenia	85 percent	82 percent
Grade 3/4 Leukopenia	80 percent	66 percent
Grade 3/4 Thrombocytopenia	10 percent	3 percent
Grade 3/4 Febrile Neutropenia	8 percent	13 percent
Grade 3/4 Anemia	7 percent	3 percent
Serious adverse events	30 percent	38 percent
Discontinuation rate due to adverse events	13 percent	28 percent

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