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FDA Approves Lilly's Gemzar(R) For Ovarian Cancer Treatment

Marks Fourth U.S. Indication for Lilly Anti-Cancer Agent

INDIANAPOLIS, July 17, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Today, Eli Lilly and Company (NYSE: LLY) announced that the United States Food and Drug Administration (FDA) has approved GEMZAR(R) (gemcitabine HCl) for use in the treatment of women living with recurrent ovarian cancer. This marks the fourth approval GEMZAR, an anti-cancer agent, has been granted by the FDA.

"Ovarian cancer is a devastating disease and we're honored that Lilly's research and innovation have brought about a clinical advance for women living with this disease," said Richard Gaynor, M.D., vice president of cancer research and global oncology platform leader at Lilly.

"Ovarian cancer is marked by one of the highest recurrence rates of all women's cancers, and when it does progress, it is frequently accompanied by significant symptoms that impede daily activities," said Robert Ozols, M.D., Ph.D. of the Fox Chase Cancer Center in Philadelphia. "The GEMZAR combination can help us aggressively address this recurrent disease with increased clinical efficacy and generally manageable side effects."

The FDA approval specifies that GEMZAR be used in combination with carboplatin, a widely-used agent, for women with advanced ovarian cancer that has relapsed at least six months after initial therapy. Clinical data submitted to the FDA showed that patients treated with a combination of GEMZAR and carboplatin experienced a significant improvement in progression-free survival and response rates compared to carboplatin alone. Progression-free survival, the amount of time a woman lives before her disease recurs or worsens, is particularly important in ovarian cancer. Ovarian cancer, which is the eighth most common cancer among women(1), recurs in approximately 90 percent of those who are diagnosed and treated for the first time. According to the American Cancer Society, there will be an estimated 20,180 new cases of ovarian cancer in America in 2006.

"The GEMZAR and carboplatin combination offers one of the most active treatment regimens available for a platinum-sensitive disease with less risk of having neurotoxicity and significant alopecia, making this a valuable treatment option for the treatment of recurrent platinum-sensitive ovarian cancer," said Tate Thigpen, M.D., professor of medicine and director of oncology at the University of Mississippi School of Medicine.

Gaynor added that Lilly Oncology sees the GEMZAR approval as a first step in ovarian cancer for the Lilly Oncology franchise. Lilly is committed to using the latest technologies and medicines to help women living with ovarian cancer. Lilly Oncology is currently evaluating other potential treatments for refractory ovarian cancer that are in earlier stages of development.

GEMZAR, which is celebrating its tenth anniversary in the U.S., is approved in more than 90 countries and last year generated sales of $1.3 billion, making it Lilly's second best-selling drug.

About the Study

Jacobus Pfisterer, M.D., Ph.D., current president of the Gynecologic Cancer Intergroup (GCIG), and professor of gynecology and obstetrics at the University of Heidelberg in Germany, was the principal investigator of the GEMZAR plus carboplatin study. The randomized Phase III study compared GEMZAR plus carboplatin against carboplatin (a platinum-based chemotherapy) alone in locally advanced or metastatic disease in patients previously treated with platinum-based therapy such as carboplatin or cisplatin. The primary endpoint of this 356-patient trial was progression-free survival, the measure of time after cancer is treated until the disease begins to worsen. Many ovarian cancer patients will receive additional treatments each time their disease recurs. Progression-free survival as an endpoint is a meaningful measurement because it is not influenced by subsequent treatments. Response rate, safety and survival were secondary endpoints.

Results showed a median progression-free survival increase of 48 percent -- a finding that was statistically significant -- in the GEMZAR and carboplatin arm compared to the carboplatin arm (8.6 months vs. 5.8 months, p=.0038). The GEMZAR combination demonstrated a two-fold increase in complete response rate -- disappearance of tumor -- over carboplatin alone (14.6 percent vs. 6.2 percent, respectively). Overall response rate for the GEMZAR combination was significantly higher than carboplatin alone, with 47 percent and 31 percent of the patients responding respectively (p=.0016).

The most commonly observed side effect of the GEMZAR and carboplatin combination therapy in this study was a decrease in white blood cell counts (known as neutropenia); the rate of serious infection was limited (less than three percent). As anticipated when cytotoxic combination therapy is compared with a cytotoxic single agent, toxicity was observed more frequently in the combination arm. Grade 3 and 4 toxicities were primarily hematological laboratory toxicities, such as anemia and thrombocytopenia (a decrease in platelets that may result in easy bruising or excessive bleeding). However, these laboratory toxicities infrequently resulted in meaningful side effects such as febrile neutropenia and Grade 3 hemorrhage.

In clinical studies, side effects were generally manageable. There have been rare reports of serious kidney, lung or liver toxicity with GEMZAR treatment. GEMZAR treatment will likely not be appropriate for women who are pregnant, may be pregnant or are nursing.

For complete safety information, please visit www.GEMZAR.com.

About 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 their physicians. Inspired by 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. P-LLY

GEMZAR(R) (gemcitabine HCl, Lilly)

This press release contains forward-looking statements about the potential of GEMZAR for the treatment of ovarian 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 that the product 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.

(1) American Cancer Society, "How Many Women Get Ovarian Cancer?" November 29, 2005, American Cancer Society, http://www.cancer.org/docroot/CRI/content/CRI_2_2_1X_How_many_women_get_ovaria n_cancer_33.asp?sitearea= (June 21, 2006).

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