May 19, 2004

# FDA Grants Approval for Lilly's Gemzar in Combination with Taxol as First-Line Treatment for Metastatic Breast Cancer

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The U.S. Food and Drug Administration has granted approval of Gemzar® (gemcitabine HCl), in combination with Taxol® (paclitaxel), providing a new option in first-line therapy for women battling metastatic breast cancer.

The FDA's approval marks the second indication in 2004 for a Lilly Oncology drug, and for Gemzar, specifically; this is the drug's third indication in the United States.

The approval of the Gemzar/Taxol combination was granted following analysis of Phase III data, which demonstrated superior treatment outcomes. Patients diagnosed with metastatic breast cancer and treated with a combination of Gemzar and Taxol experienced a significant delay in the improvement in time to disease progression of their disease and response rate compared to Taxol alone. The time to disease progression data (5.2 months vs. 2.9 months, respectively; $p<0.0001$) were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in 2003. Survival results will be formally presented at the 2004 ASCO meeting, June 5-8 in New Orleans.

"The Gemzar/Taxol combination is one of the few combinations to surpass the single-agent efficacy of Taxol," said Paolo Paoletti, M.D. vice president of oncology clinical research at Eli Lilly and Company (NYSE: LLY). "In a disease that is marked by high recurrence rates, this added benefit is welcome news to patients and physicians."

The official label on the approval states that Gemzar, in combination with paclitaxel, is approved in the United States for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.

In addition to the United States, Gemzar has been approved for this indication in 32 countries as of today.

**About Breast Cancer**

According to the World Health Organization, more than 1 million cases of breast cancer will be diagnosed in 2004. Breast cancer is the most common malignancy in women. In the U.S., breast cancer is one of the leading causes of cancer deaths, with 40,580 estimated deaths in 2004. About 40 percent of breast cancer patients develop metastatic breast cancer after receiving treatment during the primary breast cancer phase and the average survival time for patients after diagnosis of metastatic disease is 18 to 30 months.

**Quick Links for the Media**

Resource materials for news media professionals about Gemzar and about breast cancer are available at LillyMedia.com.

To access the Gemzar online press kit, visit http://www.lillymedia.com/rep_guides/gemzar.html.

To access downloadable Gemzar product shots, visit the LillyMedia photo gallery.

To access downloadable Gemzar logos, visit the LillyMedia photo gallery.

**About Gemzar**

In the U.S., Gemzar was approved for the treatment of locally advanced or metastatic pancreas cancer in 1996 and, in combination with cisplatin, for the treatment of locally advanced or metastatic non-small cell lung cancer in 1998. Gemzar is approved in more than 90 countries and is the worldwide standard of care for pancreatic cancer and in many parts of the world for non-small cell lung, bladder and breast cancers. 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.

**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.

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Gemzar® (gemcitabine hydrochloride, Lilly)

Taxol® (paclitaxel, Bristol-Myers Squibb)

Gemzar