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FDA Approves Lilly's Alimta (pemetrexed) for the Second-Line Treatment of Advanced Lung Cancer

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Accelerated Approval Results in Second U.S. Indication in Six Months for Alimta

INDIANAPOLIS - Today, Eli Lilly and Company's anti-cancer drug Alimta[®] (pronounced: "uh-LIMB-ta") received its second U.S. approval in 2004. The U.S. Food and Drug Administration granted accelerated approval for Alimta for the treatment of locally advanced or metastatic non-small cell lung cancer in previously treated patients. In February, Alimta was approved, in combination with cisplatin (a common chemotherapy agent), for the treatment of malignant pleural mesothelioma, a cancer often associated with asbestos exposure.

"Alimta's development is a demonstration of our commitment to patients with cancer and is testament to our emergence as a leader in oncology," said Sidney Taurel, Lilly's chairman, president and chief executive officer. "With the advances we are making - and will continue to make - via our existing and future oncology products, we are confident that Lilly will emerge as one of the premier oncology companies in the world."

Over the past decade, lung cancer rates have continued to rise and now the disease is the leading cause of cancer death in men and women. According to the American Cancer Society, approximately 174,000 individuals in the U.S. are diagnosed with lung cancer each year.

Fortunately, developments in chemotherapy, including Lilly's Gemzar[®] (gemcitabine), are helping an increasing number of patients to live longer after initial treatment, or first-line therapy. But, due to the aggressive nature of lung cancer, the disease recurs in the majority of patients and only 40,000 to 50,000 are well enough to tolerate treatment in the second-line setting.

Patients treated with the current standard of care in the second-line setting, Taxotere[®] (docetaxel), usually experience severe toxic side effects such as neutropenia (a decrease in infection fighting white blood cells), neutropenia with fever, diarrhea and hair loss.

Alimta is an antifolate that simultaneously blocks three separate enzyme targets vital to the survival of cancer cells. Alimta's administration includes vitamin supplementation with folic acid and vitamin B12. A team of researchers led by Lilly discovered that this vitamin regimen significantly reduces the drug's side effects without negatively impacting its ability to kill cancer cells. The administration cycle for Alimta is a 10-minute infusion, once every three weeks.

"Alimta represents a medical advance in the treatment of lung cancer," said Paul Bunn, M.D., director of the University of Colorado Cancer Center. "The benefits Alimta offers patients are clear, and it is much better tolerated than the current standard, and is conveniently administered."

Paolo Paoletti, vice president of oncology clinical research at Lilly said, "Alimta represents a true breakthrough in cancer care and is pushing the boundaries of conventional therapies by demonstrating a good response rate, while maintaining reduced toxicity via vitamin supplementation."

The FDA accelerated approval is based on Alimta's efficacy and safety profile as evidenced in one of the largest Phase III studies to date in the second-line setting that compared Alimta directly to Taxotere. In July, the study was the basis for a unanimous recommendation for accelerated approval by the FDA's Oncologic Drug Advisory Committee.

Alimta's approval was based on the drug's ability to reduce tumor size (response rate) in advanced non-small cell lung cancer patients.

The FDA also cited Alimta's significantly improved safety profile as compared to Taxotere as a supporting basis for approval. Patients on Alimta also experienced less Grade 3 or 4 neutropenia (a decrease in infection-fighting white blood cell counts); less neutropenia with fever; less diarrhea; fewer hospitalizations due to adverse events and less hair loss. As with all chemotherapy agents, patients on Alimta and Taxotere experienced low-blood cell counts. Patients treated with Alimta experienced higher rates of Grade 3 or 4 Alanine Transaminase (ALT), a laboratory measurement of liver function. Some of the most common Grade 3 or 4 toxicities associated with Alimta (regardless of causality) include anemia (8 percent vs. 7

percent for Taxotere); fatigue (16 percent vs. 17 percent for Taxotere); anorexia (5 percent vs. 8 percent for Taxotere); and infection without neutropenia (6 percent vs. 4 percent for Taxotere).

In accordance with the FDA's accelerated approval, Lilly will continue to gather data for Alimta in non-small cell cancer.

Alimta's approval in second-line non-small cell lung cancer is the latest in a series of research advances by Lilly Oncology this year:

- In February, Alimta, with cisplatin, was approved by the FDA for the treatment of malignant pleural mesothelioma, a cancer associated with asbestos exposure.
- In June, the European Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for a dual indication for Alimta. The opinion recommends approval of single-agent Alimta for patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy and in combination with cisplatin for the treatment of unresectable malignant pleural mesothelioma in patients who have not received prior chemotherapy.
- In June, the FDA approved Gemzar, in combination with Taxol[®] (paclitaxel), for the front-line treatment of metastatic breast cancer, which strikes 55,000 women annually in the U.S. Gemzar's breast cancer indication marks its third U.S. approval. Gemzar is also approved for the treatment of advanced pancreatic cancer and, in combination with cisplatin, for the first-line treatment of locally advanced or metastatic lung cancer.
- Several European countries approved Gemzar, in combination with carboplatin, for the treatment of recurrent epithelial ovarian cancer. Lilly's Gemzar is also approved in Europe under national licenses either as a single-agent or combination agent for the treatment of pancreatic, bladder and first-line non-small cell lung cancers. Gemzar, in combination with paclitaxel, is approved in most European countries in the treatment of metastatic breast cancer.

For full prescribing information about Alimta or Gemzar, please go to 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, Indiana, 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.

About Lilly Oncology

Lilly Oncology, a division of Eli Lilly and Company, is a world leader in cancer research and treatment, with therapies that are considered a standard of care in a number of difficult-to-treat tumor types built upon a vibrant and cutting edge research platform driving therapeutic innovation. Lilly Oncology is committed to delivering realistic solutions to physicians, patients and payers that materially improve the course of cancer care. With a promising pipeline of innovative products built on strong scientific foundations, Lilly strives to continually find ways to offer hope in the way of answers for patients.

This press release contains forward-looking statements about the potential of Alimta for the treatment of second-line non-small cell lung 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 prove 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.

Alimta[®] (pemetrexed, Lilly)
Gemzar[®] (gemcitabine HCl, Lilly)
Taxotere[®] (docetaxel, Aventis)
Taxol[®] (paclitaxel, Bristol-Myers Squibb)

