



## **Lilly Receives Fourth FDA Approval for ALIMTA(R) (pemetrexed for injection)**

### **--ALIMTA First Chemotherapy Approved As Maintenance Therapy For Nonsquamous Non-Small Cell Lung Cancer**

INDIANAPOLIS, July 6, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today it received a fourth approval from the U.S. Food and Drug Administration (FDA) for ALIMTA(R) (pemetrexed for injection). The latest approval is for ALIMTA as a maintenance therapy for locally advanced or metastatic non-small cell lung cancer (NSCLC), specifically for patients with a nonsquamous histology whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. ALIMTA is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

NSCLC is the most common form of lung cancer, resulting in more than 180,000 new cases in the U.S. each year.(1),(2) It is defined as a group of histologies, that is, tumor types differentiated by cellular structure. Nonsquamous histology includes adenocarcinoma and large cell carcinoma, which account for more than half of all NSCLC diagnoses,(3) as well as histologies classified as "other."

"This FDA approval is encouraging news for non-small cell lung cancer patients, their caregivers and doctors," said Richard Gaynor, M.D., vice president of cancer research and global oncology platform leader for Lilly. "It represents an important paradigm shift for NSCLC treatment - maintenance therapy as a way of extending survival in nonsquamous patients, using histology as a way of determining which NSCLC patients may benefit and which may not.

"Previously, patients received best supportive care following their chemotherapy. Now physicians and patients have a new option to improve survival," added Gaynor.

The notion of maintenance therapy in NSCLC is new. Maintenance therapy is treatment given after initial chemotherapy but before new tumor growth. And while pathologists routinely determine the cancer's histology, or tissue type, the use of this information to tailor therapy for potentially better outcomes is also new.

Results from a global, multicenter, double-blind Phase III trial were presented as an oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting in Orlando, Fla. on May 31, 2009 (Abstract # CRA8000) by Chandra Belani, M.D., Miriam Beckner distinguished professor of medicine and deputy director of Penn State Cancer Institute at Penn State Milton S. Hershey Medical Center.

The trial compared efficacy with respect to overall survival of ALIMTA plus best supportive care versus placebo plus best supportive care in 663 patients with stage IIIB/IV NSCLC whose disease had not progressed after four cycles of platinum-based induction chemotherapy. The trial supported previous studies looking at the use of histology to tailor treatment for patients with advanced nonsquamous NSCLC.

Patients in the trial were treated with ALIMTA (500 mg/m<sup>2</sup> on day one of each 21-day cycle) plus best supportive care or placebo plus best supportive care. All patients were supplemented with vitamin B12, folic acid and dexamethasone.

In 2004, ALIMTA received consecutive approvals: it was the first agent to be approved in combination with cisplatin as a treatment for patients with malignant pleural mesothelioma, whose disease is unresectable or who are otherwise not candidates for curative surgery, and then as a single agent for the second-line treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy treatment.(4)

In 2008, ALIMTA, in combination with cisplatin, was approved as a first-line treatment for locally advanced or metastatic NSCLC for patients with nonsquamous histology. At the time of the first-line approval, the FDA also approved a change to the second-line indication. ALIMTA is now indicated as a single agent for the treatment of patients with locally advanced or metastatic, nonsquamous NSCLC after prior chemotherapy. ALIMTA is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

For full prescribing and safety information about ALIMTA, visit [www.ALIMTA.com](http://www.ALIMTA.com).

Notes to Editor

## About Non-Small Cell Lung Cancer (NSCLC)

NSCLC is the most common type of lung cancer and represents 85 to 90 percent of all lung cancers.<sup>(5)</sup> NSCLC has five-tier staging, starting at 0 and rising to the severity of stage IV.<sup>(6)</sup> NSCLC can spread through the lymphatic system, penetrating the chest lining, ribs, and the nerves and blood vessels that lead to the arm. The liver, bones and brain are potential targets if the cancerous cells enter the bloodstream.

According to the World Health Organization (WHO) Cancer Report, lung cancer is the world's most common cancer and the leading cause of cancer death for men and women. More than 1 million people die from lung cancer each year.<sup>(7)</sup>

## About Lilly Oncology

For more than four decades, Lilly has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Because no two cancer patients are alike, Lilly Oncology is committed to developing novel treatment approaches. To learn more about Lilly's commitment to cancer, please visit [www.LillyOncology.com](http://www.LillyOncology.com).

## About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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

ALIMTA(R) (pemetrexed for injection), Lilly

### Important Safety Information for ALIMTA

ALIMTA is approved by the FDA in combination with cisplatin (another chemotherapy drug) for the initial treatment of advanced nonsquamous non-small cell lung cancer (NSCLC), a specific type of NSCLC. ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is approved by the FDA for the treatment of patients with advanced nonsquamous nonsmall cell lung cancer (NSCLC), a specific type of NSCLC, to maintain the effect of initial treatment with chemotherapy and whose disease has not worsened. ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is approved by the FDA as a single agent (used alone) for the treatment of patients with advanced nonsquamous non-small cell lung cancer (NSCLC), a specific type of NSCLC, after prior chemotherapy. ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is a treatment for malignant pleural mesothelioma (MPM), which is a cancer that affects the inside lining of the chest cavity. ALIMTA is given with cisplatin, another anticancer medicine (chemotherapy), when surgery is not an option.

ALIMTA may not be appropriate for some patients. If you are allergic to ALIMTA, tell your doctor because you should not receive it. If you think you are pregnant, are planning to become pregnant, or are nursing, please tell your healthcare team. ALIMTA may harm your unborn or nursing baby. Your physician may advise you to use effective contraception (birth control) to prevent pregnancy while you are being treated with ALIMTA.

If you have liver or kidney problems, be sure to tell your doctor. Your dose of ALIMTA may have to be changed, or ALIMTA may not be right for you. There is a risk of side effects associated with ALIMTA therapy. ALIMTA can suppress bone marrow function. It is very important to take folic acid and vitamin B12 prior to and during your treatment with ALIMTA to lower your chances of harmful side effects.

Your healthcare professional will prescribe a medicine called a corticosteroid, which lowers your chances of getting skin reactions with ALIMTA. Ask your healthcare professional before taking medicines called NSAIDs (nonsteroidal anti-inflammatory drugs used to treat pain or swelling). Tell your doctor if you are taking other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements.

The most common side effects of ALIMTA when given alone or in combination with cisplatin, another chemotherapy drug, are low blood cell counts (red blood cells, white blood cells, and platelets); tiredness; stomach upset, including nausea, vomiting,

and diarrhea; mouth, throat, or lip sores; loss of appetite; rash; and constipation.

Call your healthcare professional right away if you have a fever, chills, diarrhea, or mouth sores. These symptoms could mean you have an infection. These are not all of the side effects of ALIMTA. If you have any side effect that bothers you or that does not go away, be sure to talk with your healthcare professional.

You will have regular blood tests before and during your treatment with ALIMTA. Your doctor may adjust your dose of ALIMTA or delay your treatment based on the results of your blood test and on your general condition.

For more information about all of the side effects of ALIMTA, please talk with your healthcare team, see the Patient Prescribing Information and full Prescribing Information, visit [www.ALIMTA.com](http://www.ALIMTA.com), or call 1-800-545-5979.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

This press release contains forward-looking statements about the potential of ALIMTA for the treatment of 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, commercialization, and regulatory review. 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, "What Is Non-Small Cell Lung Cancer?," October 15, 2007, American Cancer Society, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1x\\_What\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer.asp?rnav=crl](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Non-Small_Cell_Lung_Cancer.asp?rnav=crl), (February 21, 2008).

(2) American Cancer Society, "What Are the Key Statistics About Lung Cancer?," October 15, 2007, American Cancer Society, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1x\\_What\\_Are\\_the\\_Key\\_Statistics\\_About\\_Lung\\_Cancer\\_15.asp?rnav=crl](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Are_the_Key_Statistics_About_Lung_Cancer_15.asp?rnav=crl), (September 19, 2008).

(3) American Cancer Society. What is Non-Small Cell Lung Cancer? Available at: [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1x\\_What\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer.asp?sitearea=](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Non-Small_Cell_Lung_Cancer.asp?sitearea=). Accessed May 1, 2009.

(4) NOTE: The 2nd-line NSCLC indication was approved under 21 CFR 314.500 et seq (Subpart H - Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) using a surrogate endpoint.

(5) American Cancer Society, "What Is Non-Small Cell Lung Cancer?," October 15, 2007, American Cancer Society, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1x\\_What\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer.asp?rnav=crl](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Non-Small_Cell_Lung_Cancer.asp?rnav=crl), (February 21, 2008).

(6) American Cancer Society, "How Is Non-Small Cell Lung Cancer Staged?" October 15, 2007, American Cancer Society, [www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_3x\\_How\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer\\_Staged.asp?rnav=crl](http://www.cancer.org/docroot/CRI/content/CRI_2_4_3x_How_Is_Non-Small_Cell_Lung_Cancer_Staged.asp?rnav=crl), (February 21, 2008).

(7) World Health Organization, Gender in Lung Cancer and Smoking Research, Department of Gender, Women and Health, 2003, <http://www.who.int/gender/documents/en/lungcancerlow.pdf>.

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