



## Two Studies Evaluated Full-Dose Chemotherapy Regimen and Concurrent Radiation in Treatment of Lung Cancer

INDIANAPOLIS, May 20, 2010 /PRNewswire via COMTEX News Network/ -- Results of two Phase II trials evaluating ALIMTA(R) (pemetrexed for injection) in combination with a platinum chemotherapy and radiation for patients with locally advanced non-small cell lung cancer (NSCLC) will be presented by Eli Lilly and Company at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill., on June 6, 2010.

The standard of care for many patients with unresectable stage IIIA/B NSCLC is a concurrent treatment of chemotherapy and radiation, but the chosen chemotherapy varies by oncologist. Previous study results for an ALIMTA-based regimen in this therapeutic area warranted further study.(1)

The Phase II study (ASCO Abstract #7087) evaluated 39 patients with unresectable stage IIIA/B NSCLC who were treated with full doses of ALIMTA and cisplatin and a full dose of concurrent radiation. Patients on the ALIMTA regimen achieved a median overall survival of 19.7 months and median progression-free survival of 11.8 months. Eighty percent of patients continued to live one year following initial treatment and 47 percent of patients were living for one year without tumor progression. The single-arm trial accrued patients across five centers in Canada.

Ten patients experienced grade 3/4 hematologic toxicity, particularly neutropenia (low white blood cell count). Non-hematologic toxicities were also observed, including grade 3 nausea/vomiting, esophagitis (inflammation of the esophagus), serum sodium and potassium alterations, fatigue, and pneumonitis (inflammation of lung tissue) and grade 4 hypotension (low blood pressure).

"Early results from this Phase II study supported continuing to evaluate both of these agents at full dose," said Richard Gaynor, M.D., vice president of oncology product development and medical affairs at Lilly. "Likewise, this final Phase II evidence supports the rationale for our ongoing Phase III trial, PROCLAIM, where we are evaluating ALIMTA+cisplatin+radiation followed by ALIMTA alone as maintenance therapy in locally advanced stage III NSCLC in nonsquamous cell histology."

Another Phase II study (ASCO Abstract #7082) evaluated patients with inoperable stage IIIA/B NSCLC with a treatment regimen of ALIMTA plus either carboplatin or cisplatin along with concurrent radiation therapy. Results from those treated on the ALIMTA+carboplatin+radiation arm found 6.7% achieving a complete response, 40% with a partial response, 46.7% with stabilized disease and 6.7% with progressive disease. Results of those treated on the ALIMTA+cisplatin+radiation arm found 5% achieving a complete response, 55% with a partial response, 25% with stabilized disease and 15% with progressive disease.

Grade 3/4 toxicities on the carboplatin arm included neutropenia, thrombocytopenia (low platelet count), esophagitis, fatigue, anemia (low red blood cell count) and dysphagia (difficulty in swallowing). Grade 3 toxicities on the cisplatin arm were neutropenia, esophagitis, fatigue and anemia, while one instance of grade 4 esophagitis was observed.

### **PROCLAIM Trial**

Further evaluation of ALIMTA in this therapeutic setting is currently ongoing with the Phase III PROCLAIM study. The trial seeks to evaluate ALIMTA+cisplatin+radiation followed by ALIMTA alone as maintenance therapy versus etoposide+cisplatin+radiation followed by consolidation cytotoxic chemotherapy of choice in locally advanced stage III NSCLC in nonsquamous cell histology. The primary outcome is overall survival, and secondary outcomes include progression-free survival, toxicities, and 1-, 2-, and 3-year survival rates. Radiation quality control is a key component of the trial.

For more information about ALIMTA, please see the full prescribing information (<http://pi.lilly.com/us/alimta-pi.pdf>) and patient prescribing information (<http://pi.lilly.com/us/alimta-ppi.pdf>). You may also learn more about ALIMTA at [www.Alimta.com](http://www.Alimta.com).

### **Important Safety Information for ALIMTA (pemetrexed for injection)**

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 non-small 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 <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 <http://www.fda.gov/medwatch>, or call 1-800-FDA-1088.

## **Notes to Editor**

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

Globally, lung cancer is the most common form of cancer and the biggest killer, causing 1.3 million cancer deaths annually.(2) About 85 - 90 percent of all lung cancers are NSCLC.(3) NSCLC has five-tier staging, starting at 0 and rising to the severity of stage IV.(4) 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.

NSCLC comprises a group of histologies or tumor types differentiated by cellular structure. Nonsquamous histology includes adenocarcinoma and large cell carcinoma, which account for more than half of all NSCLC diagnoses,(4) as well histologies classified as "other."

### **About Lilly Oncology**

For more than four decades, Lilly Oncology, a division of Eli Lilly and Company, 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 Lilly

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. Additional information about Lilly is available at [lilly.com](http://lilly.com).

## P-LLY

*This press release contains forward-looking statements about the potential of ALIMTA and platinum chemotherapy in combination with radiation therapy 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 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) *J Clin Oncol* 26: 2008 (May 20 suppl; abstr 7550)

(2) 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>.

(3) American Cancer Society, "What Is Non-Small Cell Lung Cancer?," October 20, 2009, American Cancer Society, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1x\\_What\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer.asp?rnav=cri](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Is_Non-Small_Cell_Lung_Cancer.asp?rnav=cri). Accessed March 16, 2010.

(4) American Cancer Society, "How Is Non-Small Cell Lung Cancer Staged?" October 20, 2009, American Cancer Society, [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_3x\\_How\\_Is\\_Non-Small\\_Cell\\_Lung\\_Cancer\\_Staged.asp?rnav=cri](http://www.cancer.org/docroot/CRI/content/CRI_2_4_3x_How_Is_Non-Small_Cell_Lung_Cancer_Staged.asp?rnav=cri). Accessed March 16, 2010.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO> )

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