



Study Published in The Lancet Showed Significant Survival Benefit for Patients Facing Deadly Form of Lung Cancer

Study Evaluated Lilly's ALIMTA(R) (pemetrexed for injection) versus Placebo as Maintenance Therapy in Advanced Non-Small Cell Lung Cancer Patients

INDIANAPOLIS, Sept 21, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Data published today in The Lancet showed a survival benefit in nonsquamous patients with advanced non-small cell lung cancer (NSCLC) who received maintenance therapy with ALIMTA(R) (pemetrexed for injection) plus best supportive care as compared to placebo plus best supportive care.

This Phase III clinical trial supported previous studies looking at the use of histology to tailor treatment with ALIMTA for patients with advanced nonsquamous NSCLC. Advanced nonsquamous NSCLC patients on the ALIMTA plus best supportive care arm achieved more than five months increased median overall survival compared to nonsquamous NSCLC patients who received placebo plus best supportive care following initial chemotherapy.

The publication of The Lancet manuscript follows the July 2009 U.S. Food and Drug Administration (FDA) approval of ALIMTA as maintenance therapy for patients with locally advanced or metastatic nonsquamous NSCLC, whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. ALIMTA is not indicated for treatment in patients with squamous cell NSCLC. The European Commission also granted a similar approval in July 2009.

NSCLC 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 about 70 percent of all NSCLC diagnoses(1) - as well as histologies classified as "other." About 30 percent of all NSCLC cases are squamous.(2)

Maintenance therapy is a relatively new concept in NSCLC treatment, according to study lead author Chandra P. 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 in Hershey, Pa.

"Previously, we would treat patients with advanced non-small cell lung cancer with four cycles of a platinum-based therapy, and then wait for a recurrence before treating again," said Dr. Belani. "The results of this study are provocative and introduce the concept of maintenance therapy for patients with non-small cell lung cancer."

"What makes these findings more compelling is a survival advantage exceeding five months with ALIMTA for patients with nonsquamous cell histologies. The degree of patient benefit is substantial," added Dr. Belani.

"This study is very encouraging for our fight against this deadly disease," added Richard Gaynor, M.D., Lilly's vice president of cancer research and global oncology platform leader. "First, it makes a case for maintenance therapy in advanced, nonsquamous NSCLC. Secondly, it showcases the importance of histology in tailoring a treatment to the nonsquamous NSCLC patient."

The Lancet manuscript of ALIMTA as a maintenance therapy for advanced nonsquamous NSCLC summarized findings from a global, multicenter, double-blind Phase III trial that was presented by Dr. Belani in an oral presentation at the American Society of Clinical Oncology (ASCO) annual meeting in Orlando, Fla. on May 31, 2009.(3)

The trial compared the efficacy 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.

According to the results, patients treated with ALIMTA demonstrated statistically superior overall survival compared to those treated with placebo (13.4 months vs. 10.6 months). But when breaking down the data by histology, researchers found nonsquamous patients on the ALIMTA arm achieved 15.5 months median overall survival compared to 10.3 months for nonsquamous patients on the placebo arm. Patients with squamous cell carcinoma who were treated with ALIMTA did not see an improvement in overall survival as compared to placebo (9.9 vs. 10.8 months, respectively).

Patients in the trial were treated with ALIMTA (500 mg/m² on day one of each 21-day cycle) or placebo. All patients were

supplemented with vitamin B12, folic acid and dexamethasone.

Drug-related grade 3/4 toxicities were higher for those treated with ALIMTA vs. placebo (16% vs. 4%); specifically, anemia (3% vs. 1%), neutropenia (3% vs. 0%), leucopenia (2% vs. 1%), fatigue (5% vs. 1%), anorexia (2% vs. 0%), mucositis/stomatitis (1% vs. 0%), diarrhea (1% vs. 0%), infection (2% vs. 0%), and neuropathy-sensory (1% vs. 0%). Increases in adverse reactions (all grades) were observed with longer exposure. Grade 3/4 toxicities did not increase significantly in patients who received greater than or equal to six cycles and greater than or equal to ten cycles of ALIMTA.

ALIMTA is also approved for: first-line treatment of advanced, nonsquamous NSCLC in combination with a platinum-based chemotherapy; as a single agent in the second-line setting for advanced, nonsquamous NSCLC patients with recurrent disease; and 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.

For full prescribing and safety information about ALIMTA, visit www.ALIMTA.com.

Notes to Editor

About Non-Small Cell Lung Cancer (NSCLC)

Globally, lung cancer impacts more than 3 million people and is one of the most common cancers worldwide, accounting for 1.2 million new cases annually.(4) About 85 - 90 percent of all lung cancers are NSCLC.(5)(6)

About Lilly Oncology, a Division of Eli Lilly and Company

For more than four decades, Lilly Oncology 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. Our quest is to develop a broad portfolio of tailored therapies that 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

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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 non-squamous 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 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, 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. 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.

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

(1) The Wellness Community, "Understanding Lung Cancer," Available at: <http://www.thewellnesscommunity.org/mm/Learn-About/cancertype/lungcancer/Undertstanding-Lung-Cancer.aspx>. Accessed July 24, 2009.

(2) The Wellness Community, "Understanding Lung Cancer," Available at: <http://www.thewellnesscommunity.org/mm/Learn-About/cancertype/lungcancer/Undertstanding-Lung-Cancer.aspx>. Accessed July 24, 2009.

(3) C. P. Belani, T. Brodowicz, et al. Maintenance pemetrexed (Pem) plus best supportive care (BSC) versus placebo (Plac) plus BSC: A randomized phase III study in advanced non-small cell lung cancer (NSCLC). Abstract #CRA8000. 2009 American Society of Clinical Oncology (ASCO) Annual Meeting. J Clin Oncol 27:18s, 2009 (suppl; abstr CRA8000).

(4) World Health Organization: Global cancer rates could increase by 50% to 15 million by 2020, Fact sheet. Available at: <http://www.who.int/mediacentre/news/releases/2003/pr27/en/>. Accessed July 10, 2009.

(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?nav=cri. Accessed February 21, 2008.

(6) 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?nav=cri. Accessed February 21, 2008.

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