



## **New Study Released Today Showed Patients With Deadly Form of Lung Cancer Lived Longer Without Disease Worsening**

### **Pivotal Phase III ALIMTA study met primary endpoint**

INDIANAPOLIS, June 5, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that PARAMOUNT, its Phase III study evaluating ALIMTA® (pemetrexed for injection) in the continuation maintenance setting, met its primary endpoint of progression-free survival, or the time a patient is alive without their disease worsening, for patients with a specific type of lung cancer called advanced nonsquamous non-small cell lung cancer (NSCLC).

"Continuation maintenance" treatment is when one of the same medicines used in first-line treatment setting is continued as maintenance therapy in an effort to control the cancer.

Results from the study will be presented on Sunday, June 5 at 11:30 a.m. CDT during the Lung Cancer Oral Abstract Session (Abstract #CRA7510) at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill. Lilly will present overall survival results from PARAMOUNT at a medical meeting in the future.

PARAMOUNT is the second study to evaluate the use of ALIMTA as a maintenance therapy in patients with advanced nonsquamous NSCLC, and the first study to evaluate the use of continuation maintenance with ALIMTA(1) following first-line ALIMTA plus cisplatin therapy.

Results of this multicenter, double-blind trial demonstrated the median progression-free survival measured from randomization (after first-line treatment) was 3.9 months on the ALIMTA arm as compared to 2.6 months on the placebo arm with a hazard ratio of 0.64. Said another way, the study showed that ALIMTA continuation maintenance arm resulted in a 36 percent improvement of survival without disease worsening over the placebo arm. The maintenance disease control rate, or the percentage of patients achieving either a response or stable disease first measured at 6 weeks post-randomization was 71.8 percent (2.8%/69.0%) on the ALIMTA arm and 59.6 percent (0.6%/59.0%) on the placebo arm.

"PARAMOUNT demonstrated that an ALIMTA continuation maintenance regimen—single-agent ALIMTA following ALIMTA plus cisplatin induction therapy—can improve progression-free survival in patients with the most common form of lung cancer," said Allen S. Melemed, M.D., M.B.A., ALIMTA medical product development leader at Lilly Oncology. "This finding continues to validate the use of ALIMTA maintenance treatment for certain patients living with this devastating disease."

A total of 939 patients with advanced nonsquamous NSCLC were enrolled in the study and received ALIMTA (500 mg/m<sup>2</sup> on day one of a 21-day cycle) in combination with cisplatin (75 mg/m<sup>2</sup>) induction therapy. Patients whose disease had not progressed during the ALIMTA+cisplatin induction and had a performance status of 0-1 (n=439) were randomized to receive ALIMTA maintenance (500 mg/m<sup>2</sup> on day one of a 21-day cycle) plus best supportive care (n=359) or placebo plus best supportive care (n=180) until disease progression. All patients received vitamin B12, folic acid and dexamethasone.

Overall, the most serious (grade 3/4) drug-related adverse events (AEs) were higher for those treated with ALIMTA continuation maintenance versus placebo (9.2% vs. 0.6% laboratory and 8.9% vs. 4.4% non-laboratory). The most commonly reported drug-related AEs observed on the ALIMTA arm versus placebo were anemia (4.2% vs. 0.6%), fatigue (4.5% vs. 0.6%), and neutropenia (3.6% vs. 0%). There was one potentially drug-related death on each arm. Discontinuations due to AEs were 5.3 percent with ALIMTA and 3.3 percent with placebo.

The study was conducted in patients with advanced nonsquamous NSCLC because past studies have shown that advanced NSCLC patients with a nonsquamous histology (those with adenocarcinoma, large cell carcinoma, or other subtypes) experienced improved efficacy over the relative comparator arm in the trial (an increase in progression-free survival, as well as overall survival), when treated with an ALIMTA regimen.(1,2) Patients with advanced NSCLC with squamous cell histology were not included in the PARAMOUNT study as ALIMTA has not shown to be effective in this patient population relative to the comparators in these previous trials.

### **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.(3) About 85 — 90 percent of all lung cancers are NSCLC.(4) 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(5), 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 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**

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

#### ***What is the most important information that I should know about ALIMTA?***

ALIMTA can suppress bone marrow function, which may cause low blood cell counts.

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 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.

Your doctor will prescribe a medicine called a "corticosteroid" to take for 3 days during each treatment with ALIMTA. Corticosteroids lower your chances for getting skin reactions with ALIMTA.

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.

- You must take folic acid every day for at least 5 days out of the 7 days before your first dose of ALIMTA. You must keep taking folic acid every day during the time you are getting treatment with ALIMTA, and for 21 days after your last treatment.
- Your doctor will give you vitamin B12 injections while you are getting treatment with ALIMTA. You will get your first vitamin B12 injection during the week before your first dose of ALIMTA, and then about every 9 weeks during treatment.

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.

#### ***What should I tell my doctor before receiving ALIMTA?***

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.

Tell your doctor if you are taking other medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements. ALIMTA and other medicines may affect each other, causing serious side effects. Especially, tell your doctor if you are taking medicines called "nonsteroidal anti-inflammatory drugs" (NSAIDs) for pain or swelling.

## ***What are the possible side effects of ALIMTA?***

Most patients taking ALIMTA will have side effects. Sometimes it is not always possible to tell whether ALIMTA, another medicine, or the cancer itself is causing these side effects.

**Call your doctor right away if you have a fever, chills, diarrhea, or mouth sores.** These symptoms could mean you have an infection, which may be severe and could lead to death.

The most common side effects of ALIMTA when given alone or in combination with cisplatin are:

- **Stomach upset, including nausea, vomiting, diarrhea, or constipation.** You can obtain medicines to help control some of these symptoms. Call your doctor if you get any of these symptoms.
- **Low blood cell counts:**
  - **Low red blood cells.** Low red blood cells may make you feel tired, get tired easily, appear pale, and become short of breath.
  - **Low white blood cells.** Low white blood cells may give you a greater chance for infection. If you have a fever (temperature above 100.4 degrees F) or other signs of infection, call your doctor right away.
  - **Low platelets.** Low platelets give you a greater chance for bleeding. Your doctor will do blood tests to check your blood counts before and during treatment with ALIMTA.
- **Tiredness.** You may feel tired or weak for a few days after your ALIMTA treatments. If you have severe weakness or tiredness, call your doctor.
- **Mouth, throat, or lip sores** (stomatitis, pharyngitis). You may get redness or sores in your mouth, throat, or on your lips. These symptoms may happen a few days after ALIMTA treatment. Talk with your doctor about proper mouth and throat care.
- **Loss of appetite.** You may lose your appetite and lose weight during your treatment. Talk to your doctor if this is a problem for you.
- **Rash.** You may get a rash or itching during treatment. These usually appear between treatments with ALIMTA and usually go away before the next treatment. Rarely, these reactions may be severe (can lead to Stevens-Johnson syndrome or toxic epidermal necrolysis) and could lead to death. Call your doctor if you get a severe rash, itching, or blistering.

Talk with your doctor, nurse, or pharmacist about any side effect that bothers you or that doesn't go away.

These are not all the side effects of ALIMTA. For more information, ask your doctor, nurse, or pharmacist.

## ***How is ALIMTA given?***

ALIMTA is slowly infused (injected) into a vein. The injection or infusion will last about 10 minutes. You will usually receive ALIMTA once every 21 days (3 weeks).

**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.**

PM\_CON\_ISI\_All\_121010

(1) Ciuleanu T, et al. Maintenance pemetrexed plus best supportive care versus placebo plus best supportive care for non-small-cell lung cancer: a randomised, double-blind, phase 3 study. *The Lancet*, Vol. 374 No. 9699 pp 1432-1440, October 24,

2009.

(2) Scagliotti G, Purvish P, et al. Phase III study of pemetrexed plus cisplatin versus gemcitabine plus cisplatin in chemo-naïve patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Abstract PRS-3, 12th World Conference on Lung Cancer (WCLC) 2007. Journal of Thoracic Oncology, Vol 2 No 8, Supplement 4, Page S306, August 2007.

(3) 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>, (April 20, 2011).

(4) American Cancer Society, "What Is Non-Small Cell Lung Cancer?," December 16, 2010, American Cancer Society, <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer>, (April 20, 2011).

(5) American Cancer Society, "What Is Non-Small Cell Lung Cancer?," October 20, 2009, American Cancer Society, <http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer>, (April 20, 2011).

(Logo: <http://photos.prnewswire.com/prnh/20031219/LLYLOGO> )

SOURCE Eli Lilly and Company

News Provided by Acquire Media