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## **Lung Cancer Study Showed Encouraging Results For ALIMTA-based Regimens And Full-dose Radiation**

### **Phase II trial results support ongoing registration study, PROCLAIM, which is currently enrolling patients**

INDIANAPOLIS, June 4, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced results of a Phase II trial evaluating ALIMTA® (pemetrexed for injection) in combination with a platinum chemotherapy and radiation for patients with locally advanced non-small cell lung cancer (NSCLC). The findings will be presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill. on June 4, 2012.

"The current standard of care for many patients facing this type of lung cancer is treatment with chemotherapy and radiation together," said Hak Choy M.D., professor and chairman of radiation oncology at the University of Texas Southwestern Medical Center. "Yet, there is no true consensus on the chemotherapy regimens that can be combined well with full-dose radiation. It is our hope that these results begin to consolidate the choices an oncologist has to make when beginning treatment."

The open-label randomized trial (ASCO Abstract #7002) evaluated 98 patients with inoperable stage IIIA/B NSCLC who were randomized one-to-one to receive either ALIMTA (500 mg/m<sup>2</sup>) plus carboplatin (AUC5) or ALIMTA (500 mg/m<sup>2</sup>) plus cisplatin (75 mg/m<sup>2</sup>) intravenously every 21 days for three cycles. All patients received concurrent radiation treatment (64-68 Gy [2 Gy/day for five days per week from days 1-45]). Three weeks after completion of radiation treatment, patients received consolidation treatment with ALIMTA (500 mg/m<sup>2</sup>) every 21 days for three cycles.

Patients treated on the ALIMTA+carboplatin+radiation arm achieved 18.7 months median overall survival (95% CI) for a two-year overall survival rate of 45.2% (95% CI, 29.3-59.8 months). Those treated on the ALIMTA+cisplatin+radiation arm achieved 27.0 months overall survival (95% CI) for a two-year overall survival rate of 57.6% (95% CI, 41.6-70.7 months).

Median time to disease progression was 8.8 months for those treated on the ALIMTA + carboplatin + radiation arm compared to 13.1 months for those treated on the ALIMTA + cisplatin + radiation arm.

Patients treated on the ALIMTA+carboplatin+radiation arm achieved 52.2% overall response rate (6.5% with a complete response, 45.7% with a partial response). Results of those treated on the ALIMTA+cisplatin+radiation arm found an overall response rate of 46.2% (3.8% with a complete response, 42.3% with a partial response).

Grade 4 toxicities reported on both arms of the study included anemia, neutropenia, thrombocytopenia and esophagitis. No drug-related deaths were reported.

These Phase II results support the ongoing Phase III study, PROCLAIM, which is studying the overall survival of patients with locally advanced nonsquamous NSCLC when treated with ALIMTA and cisplatin given at the same time as radiation followed by consolidation ALIMTA.

### **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.[1] About 85 - 90 percent of all lung cancers are NSCLC.[2] 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[3], 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.*

## **Important Safety Information**

### ***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 B(12) 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 B(12) injections while you are getting treatment with ALIMTA. You will get your first vitamin B(12) 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, lip, or food pipe sores** (stomatitis, pharyngitis, esophagitis). You may get redness or sores in your mouth, throat, or on your lips, or you may feel pain or difficulty when drinking or swallowing food. These symptoms may happen a few days after ALIMTA treatment. Talk with your doctor if you get any of these symptoms.
- **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 reactions usually appear between treatments with ALIMTA and usually go away before the next treatment. Skin reactions or rashes that include blistering or peeling may be severe and could lead to death. Call your doctor if you have any of these symptoms.

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](#), 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.**

[1] 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).

[2] 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).

[3] 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).

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