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Lilly Announces Results From Lung Cancer Study

POINTBREAK Phase III Study Did Not Meet Primary Endpoint of Improved Overall Survival in Patients with Nonsquamous Non-Small Cell Lung Cancer

INDIANAPOLIS, Sept. 6, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the Phase III POINTBREAK trial did not meet its primary endpoint of improved overall survival for patients with nonsquamous non-small cell lung cancer (NSCLC) who were randomized to receive a combination of ALIMTA[®] (pemetrexed for injection) with bevacizumab (AVASTIN[®]) and carboplatin induction followed by ALIMTA plus bevacizumab maintenance—the ALIMTA arm—compared to the combination of paclitaxel with bevacizumab and carboplatin followed by bevacizumab maintenance—the paclitaxel arm.

The study did meet one of its secondary endpoints of improved progression-free survival for the ALIMTA arm. Results will be presented on September 7 at the Chicago Multidisciplinary Symposium in Thoracic Oncology.

"Phase II results with this combination were promising and we were hoping to demonstrate an improvement in survival for nonsquamous NSCLC patients, so we are disappointed with the results of this trial," said Allen S. Melemed, M.D., M.B.A., senior medical director with Lilly Oncology. "POINTBREAK did show an improvement in progression-free survival, though this did not translate to an overall survival advantage."

Patients with previously untreated stage IIIB/IV nonsquamous NSCLC and a performance status of 0-1 (n=939) were randomized to receive ALIMTA (500 mg/m²) + carboplatin (AUC 6) + bevacizumab (15 mg/kg), along with dexamethasone and folic acid and vitamin B12 supplementation (n=472) or paclitaxel (200 mg/m²) + carboplatin (AUC 6) + bevacizumab (15 mg/kg), with dexamethasone (n=467). First-line treatments were conducted every three weeks for up to four cycles. Patients whose disease did not progress following first-line treatment received either maintenance of ALIMTA plus bevacizumab (n=292) on the ALIMTA arm, while those on the paclitaxel arm received bevacizumab as a single agent (n=298).

Overall survival for patients randomized to the ALIMTA arm achieved a median overall survival of 12.6 months versus 13.4 months for patients on the paclitaxel arm (HR 1.00; p=0.949), a result that demonstrated no statistical difference. POINTBREAK showed a statistically significant improvement in progression-free survival (6.0 months versus 5.6 months [HR 0.83; p=0.012]) in the ALIMTA arm. Secondary objectives also included overall response rate (34.1% versus 33.0%) and disease control rate (65.9% versus 69.8%), which did not show a difference between the two arms.

A pre-specified non-comparative survival analysis for a subgroup of patients treated with maintenance therapy showed a median survival of 17.7 months for the ALIMTA arm and 15.7 months for the paclitaxel arm and progression-free survival of 8.6 months and 6.9 months. Toxicity profiles differed between regimens. Significantly (p ≤ 0.025) more drug-related grade 3/4 anemia (14.5% versus 2.7%), thrombocytopenia (23.3% versus 5.6%) and fatigue (10.9% versus 5.0%) were seen on the ALIMTA arm. Significantly more grade 3/4 neutropenia (40.6% versus 25.8%), febrile neutropenia (4.1% versus 1.4%), sensory neuropathy (4.1% versus 0%) and grade 1/2 alopecia (36.8% versus 6.6%) were seen in patients on the paclitaxel arm.

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer has long been the most common cancer in the world, representing nearly 13 percent of all new cancers and causing nearly 1.4 million deaths annually.[1] About 85 to 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 as 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

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.

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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 Fahrenheit) 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 accompanying this booklet, 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. 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.

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

[1] World Health Organization International Agency for Research in Cancer, GLOBOCAN 2008, Section of Cancer Information, <http://globocan.iarc.fr/factsheets/cancers/lung.asp>, (Accessed June 20, 2012).

[2] American Cancer Society, "What Is Non-Small Cell Lung Cancer?," February 17, 2012, American Cancer Society, <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer>, (Accessed June 20, 2012).

[3] American Cancer Society, "What Is Non-Small Cell Lung Cancer?," February 17, 2012, American Cancer Society, <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer>, (Accessed June 20, 2012).

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