Lung Cancer Study Reveals Similar Outcomes for African-American and Caucasian Patients Treated With Alimta®

Lilly Committed to Evaluating Medicines in Diverse Populations

INDIANAPOLIS, Sept. 20, 2011 /PRNewswire/ -- Lung cancer, the leading cause of cancer death in the U.S., takes a particularly heavy toll on African Americans. Despite their lower smoking rates, African Americans are more likely than Caucasians to develop and die from lung cancer.(1)(2)

Today, Eli Lilly and Company (NYSE: LLY) announced results of a prospective observational study that evaluated whether ethnicity affected outcome in stage IIIB/IV non-small cell lung cancer (NSCLC) patients treated with ALIMTA® (pemetrexed for injection) in the second-line setting. The study found that the disease control rate (one of the measures for evaluating the effectiveness of NSCLC therapies) among African Americans was non-inferior to that of Caucasians.

Results of the study were announced today at the American Association for Cancer Research (AACR) annual "Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved" meeting in Washington, D.C.

"Few prospective lung cancer studies have looked at the impact of race and ethnicity on clinical outcomes," said Lee Schwartzberg, M.D., FACP, president and chief medical officer at ACORN Research, LLC and one of the study's investigators. "But as cancer researchers, determining how ethnicity influences treatment should be just as important as discovering the role of a gene mutation in predicting therapeutic success."

Disease Control Rate, or DCR, is defined as the percentage of patients with a partial or complete response to a drug, plus the percentage of patients whose disease has stabilized. DCR could be a more powerful predictor of how a drug will affect survival than the traditional measure of tumor response to therapy (the sum of complete response plus partial response).

Information on DCR was available for 267 Caucasians and 59 African Americans. The unadjusted DCR, or raw data, was 45.8 percent (27 of 59 patients) for the African American study arm and 43.4 percent (116 of 267 patients) for the Caucasian arm. The odds ratio, a measure of whether a response is more likely in one population than another, indicated the proportions were similar. This was true on the raw data, as well as after adjustment for relevant factors such as age, gender, smoking status and income.

Median survival for African American patients in the study was 6.9 months (95% CI: 4.5, 8.9) compared with 6.7 months (95% CI: 5.7, 7.9) for Caucasian patients. In addition, African American patients achieved 3.0 months (95% CI: 2.3, 4.7) of median progression-free survival compared with 2.7 months (95% CI: 2.4, 3.4) for Caucasian patients. The results indicate that the DCR was non-inferior for African American compared to Caucasian NSCLC patients receiving ALIMTA in this study.

"Traditionally, the vast majority of lung cancer studies have involved Caucasians, so physicians had no way of knowing whether the same results would hold true for other ethnic groups, such as African Americans," said Coleman Obasaju, M.D., Ph.D., senior medical director at Lilly Oncology. "These kinds of studies help us begin to close this gap and improve health outcomes for all ethnicities."

As part of Lilly's goal to improve health outcomes for individual patients, the company is increasing enrollment of diverse populations in clinical trials and making it easier for patients in minority communities to participate. Lilly's clinical trial strategy includes forming partnerships with other organizations committed to the same goal, and making efforts to educate and encourage physicians and patients to understand the importance of diverse representation in clinical trials.

About Non-Small Cell Lung Cancer (NSCLC)

Globally, lung cancer is the most common form of cancer and the biggest killer, causing 1.4 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 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 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.

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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°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, 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.

(1) American Cancer Society. "Cancer Facts & Figures 2011." http://www.cancer.org/Research/CancerFactsFigures/CancerFactsFigures/cancer-facts-figures-2011 (Accessed August 3, 2011)

(2) National Cancer Institute, "Cancer Health Disparities Fact Sheet." http://www.cancer.gov/cancertopics/factsheet/disparities/cancer-health-disparities (Accessed August 16, 2011)

(3) World Health Organization. "Cancer." http://www.who.int/mediacentre/factsheets/fs297/en/. (Accessed August 16, 2011).

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

(5) American Cancer Society. "What Is Non-Small Cell Lung Cancer?" http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer. (Accessed August 16, 2011).

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