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Lilly Launches Phase III 'GALES' Trial of ALIMTA(R) (Pemetrexed for Injection) in Small Cell Lung Cancer

Global Trial - largest ever conducted in lung cancer subgroup - currently enrolling patients

INDIANAPOLIS, Oct 20, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company has launched a major clinical trial evaluating ALIMTA (pemetrexed for injection) in extensive-stage small cell lung cancer (SCLC), a devastating and rapidly spreading form of lung cancer. This international trial, expected to be the largest ever to be conducted in SCLC(1), will assess the potential clinical benefit of pemetrexed in combination with carboplatin, a commonly-used chemotherapeutic agent, in direct comparison to the current leading treatment option of etoposide in combination with carboplatin.

The trial -- known as GALES for Global Analysis of Pemetrexed in SCLC Extensive Stage -- is a Phase III, global, multicenter, randomized, open-label study that will enroll approximately 1,820 patients with extensive-stage SCLC. The study's primary objective is to compare the overall survival after treatment with pemetrexed plus carboplatin versus etoposide plus carboplatin in previously untreated patients with extensive-stage SCLC. The principal investigator of this study is Nick Thatcher, M.D. of Christie Hospital NHS Trust in Manchester, United Kingdom.

SCLC accounts for between 15 and 20 percent of all lung cancers.(2) Although SCLC is less common than the other main category of lung cancer -- non-small cell lung cancer, SCLC tends to spread more quickly and, as a result, people are typically diagnosed with extensive disease and left without options such as surgery to remove the cancer.

"An innovative aspect of this study is that we will employ the use of pharmacogenomic analysis to assess potential biological characteristics relative to a patient's potential response to chemotherapy," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Eli Lilly and Company.

Specifically, the study will use pharmacogenomic analysis of patient- authorized tissue and blood samples to determine if there are any biological characteristics that would indicate a potentially higher clinical benefit from the ALIMTA therapy for any patient sub-population groups. Pharmacogenomics may one day help researchers find ways to "tailor" chemotherapy to patients based on their biological indication to benefit from specific treatments.

The Phase II trial results for the randomized study of pemetrexed plus carboplatin are featured in the October 20, 2006 edition of the Journal of Clinical Oncology. Preliminary results for the trial were first presented at the 2005 annual meeting of the American Society of Clinical Oncology in Orlando, Florida.(3)

In addition to comparing the overall survival between the two patient groups, the study will also assess and compare the patient groups based on the following secondary objectives:

- * Overall survival in a subgroup of patients classified as "sensitive" with respect to the results of a prospectively defined set of biomarkers
- * Objective tumor response, or the percentage of patients whose tumors shrink or disappear after treatment
- * Time to event variables, including progression-free survival, survival with Grade 4 toxicity, survival without Grade 3-4 toxicity, and time to worsening of health-related quality of life

More details on the study design and information on global recruitment sites may be found at www.clinicaltrials.gov, www.lillytrials.com, or by calling 1-877-CTLILLY (1-877-285-4559).

More About SCLC

SCLC is sometimes called "oat cell" cancer because small cell lung cancer cells resemble oat grains. Patients with SCLC are staged according to a two- stage system, being diagnosed as having either limited-stage disease or extensive-stage disease.

Approximately 65 - 70 percent of patients with SCLC present with extensive-stage disease. Untreated patients with extensive-stage SCLC have a median survival of approximately five weeks and patients treated with chemotherapy have a median survival of seven to 11 months. The current two-year survival rate for patients with extensive SCLC is less than 10 percent with current management options. Combination chemotherapy remains the primary treatment option for patients with extensive-disease SCLC. Currently, cisplatin or carboplatin in combination with etoposide are the most commonly used regimens in SCLC.(4)

About ALIMTA(R) (pemetrexed for injection)

Pemetrexed is a novel antifolate that simultaneously blocks three separate enzyme targets important to the formation of basic building blocks by which cancer cells grow and divide. It is approved, in combination with cisplatin, for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

Important Safety Information

Myelosuppression is usually the dose-limiting toxicity with pemetrexed therapy.

Pemetrexed is contraindicated in patients who have a history of severe hypersensitivity reaction to pemetrexed or to any other ingredient used in the formulation.

Warnings

Patients must be instructed to take folic acid and vitamin B12 with pemetrexed as a prophylaxis to reduce treatment-related hematologic and GI toxicities. Pemetrexed should not be administered to patients with a creatinine clearance < 45 mL/min. One patient with severe renal impairment (creatinine clearance 19 mL/min) who did not receive folic acid and vitamin B12 died of drug-related toxicity following administration of pemetrexed alone. Pemetrexed can suppress bone marrow function, as manifested by neutropenia, thrombocytopenia, and anemia (or pancytopenia). Pregnancy Category D -- pemetrexed may cause fetal harm when administered to a pregnant woman.

Precautions

Complete blood cell counts, including platelet counts and periodic chemistry tests, should be performed on all patients receiving pemetrexed. Patients should not begin a new cycle of treatment unless the ANC is > 1500 cells/mm³ and the platelet count is > 100,000 cells/mm³. Pretreatment with dexamethasone or its equivalent has been reported to reduce the incidence and severity of skin rash. The effect of third space fluid, such as pleural effusion and ascites, on pemetrexed is unknown. In patients with clinically significant third space fluid, consideration should be given to draining the effusion prior to pemetrexed administration. Caution should be used when administering ibuprofen concurrently with pemetrexed to patients with mild to moderate renal insufficiency (creatinine clearance from 45 to 79 mL/min). Patients with mild to moderate renal insufficiency should avoid taking NSAIDs with short elimination half-lives for a period of 2 days before, the day of, and 2 days following administration of pemetrexed. In the absence of data regarding potential interaction between pemetrexed and NSAIDs with longer half-lives, all patients taking these NSAIDs should interrupt dosing for at least 5 days before, the day of, and 2 days following pemetrexed administration. If concomitant administration of an NSAID is necessary, patients should be monitored closely for toxicity, especially myelosuppression, renal and gastrointestinal toxicities. Concomitant administration of nephrotoxic drugs or substances that are tubularly secreted could result in delayed clearance of pemetrexed. It is recommended that nursing be discontinued if the mother is being treated with pemetrexed. Pemetrexed should be administered under the supervision of a qualified physician experienced in the use of antineoplastic agents. Dose adjustments may be necessary in patients with hepatic insufficiency.

Dosing and Modification Guidelines

Dose adjustments at the start of a subsequent cycle should be based on nadir hematologic counts or maximum nonhematologic toxicity from the preceding cycle of therapy. Modify or suspend therapy according to the Dosage Reduction Guidelines in the full Prescribing Information.

Adverse Events

The most common adverse events (grades 3/4) with pemetrexed in combination with cisplatin for the treatment of patients with MPM were neutropenia (24%); leukopenia (16%); anemia (6%); thrombocytopenia (5%); infection without neutropenia (2%); fatigue (17%); thrombosis/embolism (6%); nausea (12%); vomiting (11%); dyspnea (11%); and chest pain (9%). The most common clinically relevant adverse events (all grades) were fatigue (80%); thrombosis/embolism (7%); nausea (84%); vomiting (58%); constipation (44%); anorexia (35%); stomatitis/pharyngitis (28%); diarrhea (26%); dyspnea (66%); chest pain (40%); and rash (22%).

Copies of the package insert can be obtained via www.ALIMTA.com or calling 1-800-LILLY-RX (545-5979).

Lilly Oncology, a Division of Eli Lilly and Company

For more than four decades, Lilly Oncology has been collaborating with cancer researchers to deliver innovative treatment choices and valuable programs to patients and physicians. Inspired by courageous patients living with cancer, Lilly Oncology is providing treatments that are considered global standards of care and developing a broad portfolio of novel targeted therapies to accelerate the pace and progress of cancer care. To learn more about Lilly's commitment to cancer, please visit www.LillyOncology.com.

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(1) Investigators Thatcher N, Socinski M, Smit E et al , Randomized Phase III Trial of ALIMTA (Pemetrexed) and Carboplatin versus Etoposide and Carboplatin in Extensive-Stage Small Cell Lung Cancer; April 13, 2006.

(2) Lung Cancer Alliance, "About Lung Cancer," <http://www.lungcanceralliance.org/facing/about.html> (October 6, 2006)

(3) Socinski M, Weissman C, Hart L, et al. A Randomized Phase II Trial of Pemetrexed/Cisplatin and Pemetrexed/Carboplatin in Extensive Stage Small Cell Lung Cancer (ES-SCLC), American Society of Clinical Oncology, Orlando, Florida, May 15 - 17, 2005, Abstract #7165

(4) Investigators Thatcher N, Socinski M, Smit E et al , Randomized Phase III Trial of ALIMTA (Pemetrexed) and Carboplatin versus Etoposide and Carboplatin in Extensive-Stage Small Cell Lung Cancer; April 13, 2006.

This press release contains forward-looking statements about the potential of ALIMTA (pemetrexed) for the treatment of extensive-disease 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 the product will receive regulatory approval for a further indication, or that it 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.

ALIMTA(R) (pemetrexed, for injection, Lilly)

For more information, please visit:
http://www.lilly.com/news/media_kits/alimta.html

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

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