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Thoracic Cancer Patients Find New Reasons for Hope with Alimta®

New data may provide important treatment advances in mesothelioma and lung cancer

BARCELONA, July 5 /PRNewswire/ -- Patients with a cancer of the lining of the lung, known as malignant pleural mesothelioma (MPM), lived longer than previously reported(1), when treated with Eli Lilly and Company's Alimta® (pemetrexed) in combination with cisplatin, according to updated data presented today at the 11th annual World Conference on Lung Cancer (WCLC).

Alimta is the first and only approved therapy to show a statistically significant survival advantage in patients suffering from this difficult-to-treat cancer(2). Alimta is also approved in the United States, the European Union and several other countries as a monotherapy for second-line non-small cell lung cancer (NSCLC).

"Before Alimta was available, patients suffering from mesothelioma had no hope -- rarely living a year after diagnosis," said Nicholas J. Vogelzang, MD, director of the Nevada Cancer Institute in Las Vegas. "At 18 months, there is still a statistically significant difference in survival, which demonstrates patients are living longer when treated with this Alimta combination. If you look out further to 24 months, 22 percent of patients treated with Alimta are still alive."

Mature data presented at WCLC represent an update from trial results from the largest randomized, Phase III mesothelioma trial ever reported involving 448 patients published in the Journal of Clinical Oncology (JCO) in July 2003(2). Today's data showed median survival of patients treated with Alimta plus cisplatin was almost thirteen (12.8) months after diagnosis and 42 percent (3.8 months) longer than patients who received cisplatin alone ($p = 0.003$).

In addition, 33 percent of mesothelioma patients treated with Alimta plus cisplatin survived 18 months compared with 23 percent treated with cisplatin alone. This difference was statistically significant ($p = 0.030$). When treated with Alimta plus cisplatin, 22 percent of patients survived 24 months compared with 17 percent receiving single-agent cisplatin ($p = 0.209$).

When Alimta is given as a single agent, the most common side effects include disorders of the blood and lymphatic system, gastrointestinal disorders, fatigue and rash. The risk and severity of side effects associated with Alimta can be controlled when used with folic acid and vitamin B12 -- a supplement unique to Alimta therapy.

Alimta Data in NSCLC Presented at WCLC

"Elderly Patients Benefit From Alimta in Second-line Treatment for Advanced NSCLC"

Non-small cell lung cancer is a disease that strikes older patients, with an estimated 63 percent of Europeans and 66 percent of U.S. lung cancer patients aged 65 or older being diagnosed(3).

"This is the first set of data for second-line use that suggests elderly patients, like younger patients, tolerate and receive benefit from a salvage chemotherapy regimen," said Karen Kelly, M.D., medical director for lung and chest cancer at the University of Colorado at Denver Health Services Center. "This exploratory subset analysis of elderly patients measuring time to progression favored the Alimta arm with a trend toward improved survival as compared to docetaxel."

Alimta showed similar median overall survival benefit when compared to Taxotere® (docetaxel) (9.5 months versus 7.7 months) in a retrospective, subset analysis of 86 patients (greater than or equal to 70 years old) in a randomized Phase III trial, in previously treated, recurrent NSCLC(4). Patients treated with Alimta experienced considerably lower incidence of neutropenia (a drop in the number of white blood cells) at 12.5 percent and febrile neutropenia (neutropenia accompanied with fever) at 2.5 percent when compared with docetaxel at 29.7 percent and 18.9 percent, respectively. While the differences between Alimta and docetaxel in time to progression (4.6 months compared to 2.9 months respectively) and median overall survival were not statistically significant, it highlights the trend toward improved survival with fewer side effects.(5)

"Does Reporting Expected Duration And Severity Of Adverse Events Provide Clinically Relevant Information When Selecting A Chemotherapy Regimen? An Example Using Pemetrexed And Docetaxel"

To better understand the full burden of toxicity on a patient, researchers analyzed the randomised Phase III trial of Alimta versus docetaxel in patients with NSCLC previously treated with chemotherapy(4).

"In clinical trials, the focus remains primarily on efficacy and grade 3/4 side effects, but rarely focuses on how long patients can expect to be without toxicity," said Shkun Bhalla, health economist at Lilly. "Combining incidence, severity and persistence of adverse events can produce information of clinical relevance for both physicians and patients when selecting a treatment."

Patients who received Alimta spent a statistically significant longer period of time without toxicity (both haematological and non-haematological) when compared to docetaxel. This analysis also showed that patients who received Alimta spent a statistically significant shorter period of time experiencing grade 3 and 4 toxicities compared to docetaxel.

About Malignant Pleural Mesothelioma

Malignant pleural mesothelioma is a cancer of the lining of the lungs. The disease is often associated with asbestos exposure and has a long latency period -- usually between 20 and 40 years. Most people are not diagnosed until the cancer is in advanced stages and treatment with surgery or radiation is not an option. It is estimated that between 10,000 and 15,000 people around the world are diagnosed annually with malignant pleural mesothelioma, though incidence numbers are expected to increase within the next few years.

About Lung Cancer

According to the most recent World Health Organization Cancer Report, lung cancer is the world's most common cancer and the leading cause of cancer death for both men and women. There will be 1.2 million cases diagnosed this year around the world.(6)

Eli Lilly and Company

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Lilly Oncology

A pioneer and industry partner, Lilly Oncology is committed to delivering innovative treatment strategies and essential support programs that advance physician care and respond to patient needs. From chemotherapies that have become standards of care to novel targeted therapies currently being investigated, Lilly has been at the forefront of cancer research for more than 40 years. Lilly Oncology continues in its spirit of innovation with a broad product pipeline representing a vibrant and cutting edge research platform, built upon extensive medical expertise and human insight.

Alimta® (pemetrexed, Lilly)
Taxotere® (docetaxel, Aventis)

(1) Vogelzang NJ, Rusthoven JJ, Symanowski J, et al. Long-Term Survival Update from the Randomized Phase III Study of Pemetrexed Plus Cisplatin vs Cisplatin in Patients with Malignant Pleural Mesothelioma. Presented at WCLC 2005.

(2) Vogelzang NJ, Rusthoven JJ, Symanowski J, et al. Randomized Phase III Study of Pemetrexed Plus Cisplatin vs Cisplatin in Patients with Malignant Pleural Mesothelioma. J Clin Oncol 21:2636-2644, July 15 2003.

(3) WHO. Globocan 2000: Cancer Incidence, Mortality, and Prevalence Worldwide, International Association of Cancer Registries. <http://www-dep.iarc.fr/>

(4) Hanna N, Shepherd F, Fossella F, Pereira J et al. Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients With Non-Small-Cell Lung Cancer Previously Treated With Chemotherapy J Clin Oncol 22:1589-1597, May 1 2004.

(5) Kelly K, Langer C, Rosell R, et al. Elderly Patients Benefit From Second-line Cytotoxic Chemotherapy for Advanced NSCLC. Presented at WCLC 2005.

(6) World Health Organization Cancer Report, WHO. Globocan 2002: Cancer Incidence, Mortality, and Prevalence Worldwide, International Association of Cancer Registries. <http://www-dep.iarc.fr/>

SOURCE Eli Lilly and Company