June 24, 2004

Alimta Receives CHMP Positive Opinion for Two Cancer Indications

June 24, 2004

Recommended for Approval to Treat Malignant Pleural Mesothelioma and Lung Cancer

Eli Lilly and Company (NYSE: LLY) announced today that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for dual cancer indications for pemetrexed. The CHMP has recommended to the European Commission that approval be granted for pemetrexed. If approved, this cancer therapy will be marketed throughout the European Union by Lilly under the brand name Alimta® (pemetrexed). Marketing authorization by the European Commission is expected later this year.

If approved, pemetrexed, in combination with cisplatin, will be the first approved drug in Europe to help patients with malignant pleural mesothelioma live longer[1] and, as a monotherapy, will be an important new alternative for patients suffering from second-line non-small cell lung cancer.[2]

The CHMP's positive opinion recommends approval of pemetrexed as a single agent for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy and in combination with cisplatin for the treatment of unresectable malignant pleural mesothelioma (MPM), a cancer of the lining of the lungs, in patients who have not received prior chemotherapy. The CHMP based its positive opinion on its review of the comprehensive data package of pemetrexed in NSCLC and MPM.

"The dual submission and positive opinion for mesothelioma and non-small cell lung cancer represent a regulatory first for Lilly," said Binh Nguyen, M.D. Ph. D., medical director of Lilly Oncology Team. "We want to thank the investigators and patients for helping us achieve these important milestones."

"We are extremely pleased by the CHMP's recommendation for approval of pemetrexed in Europe. This positive opinion validates the notable clinical efficacy and controllable side effect profile seen in clinical trials," said Paolo Paoletti, M.D., vice president of oncology clinical research at Lilly. "Following approval, pemetrexed will join another Lilly cancer-fighting agent, Gemzar, which is a leading treatment for non-small cell lung cancer in Europe. Lilly remains committed to providing hope and innovative treatments for patients with cancer."

Malignant Pleural Mesothelioma

Malignant pleural mesothelioma is a rare 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. No drug has been approved by European regulators for this disease.

Non-Small Cell 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.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class 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.

References

1. Hanna N, Shepherd FA, Fossella FV, et al. Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients with Non-Small Cell Lung Cancer Previously Treated with Chemotherapy. *Journal Clinical Oncology, Vol. 22, pp. 1589-1597;* May 1, 2004.
2. Hanna N, Shepherd FA, Fossella FV, et al. Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients with Non-Small Cell Lung Cancer Previously Treated with Chemotherapy. *Journal Clinical Oncology, Vol. 22, pp. 1589-1597;* May 1, 2004.