

Eli Lilly Reports European Commission Has Approved Alimta For Use In Europe

INDIANAPOLIS — Eli Lilly and Co. on Sept. 22 announced that the European Commission (EC) has granted marketing authorization for its chemotherapy agent, Alimta (pemetrexed), for patients suffering from malignant pleural mesothelioma and non-small-cell lung cancer.

According to Eli Lilly, getting over this regulatory hurdle means that now Alimta can be offered to the two different cancer patient groups. The product launch and availability of Alimta will vary in each European member state, Eli Lilly said. Alimta, in combination with cisplatin, is now the first approved chemotherapy drug in Europe for patients diagnosed with mesothelioma.

"We are extremely pleased by the European Commission's approval of Alimta in Europe. This is an historic day — two patient groups benefit from today's approval," said Edmundo Muniz, M.D., Ph.D., oncology leader at Eli Lilly.

The EC grant followed a June 24 approval by the European Committee for Medicinal Products for Human Use (CHMP) that gave a positive opinion for dual cancer indications for Alimta and recommended to the EC that approval be granted for the drug. According to Eli Lilly, the CHMP recommendation included the approval of Alimta as a single agent for patients with locally advanced or metastatic cell lung cancer after prior chemotherapy and in combination with cisplatin for the treatment of unresectable malignant pleural mesothelioma in patients who have not received prior chemotherapy.

That recommendation followed the Feb. 5 announcement by Eli Lilly that the U.S. Food and Drug Administration had approved Alimta for use in the United States for mesothelioma patients who are not candidates for surgery.

According to Eli Lilly, the combination of Alimta and cisplatin in a clinical trial of 448 patients from 19 countries compared with cisplatin alone showed a 30 percent increase in the survival rate for those who took the drug cocktail. The same study showed that 50.3 percent of patients treated with the combination of Alimta and cisplatin were alive a year later, compared with 38 percent of those treated with just cisplatin alone, Eli Lilly reported.

Eli Lilly reported that between 10,000 and 15,000 people worldwide are diagnosed annually with malignant pleural mesothelioma. ■