

*In collaboration with the Food and Drug Administration (FDA), and as a service to our members, the Oncology Nursing Society will provide information about newly approved therapies for cancer patients. This will allow the FDA to inform ONS members of recent approvals in a timely manner. Included in the information from the FDA will be a link to the product label, which will provide the relevant clinical information on the indication, contraindications, dosing, and safety. In sending this information, ONS does not endorse any product or therapy and does not take any position on the safety or efficacy of the product or therapy described. The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:*

On September 26, 2008, the U. S. Food and Drug Administration (FDA) approved pemetrexed injection (Alimta® Injection, Eli Lilly and Company) for use in combination with cisplatin therapy for the initial treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC). Pemetrexed is not indicated for treatment of patients with squamous cell lung carcinoma.

A multicenter, randomized, open-label study in 1725 patients with stage IIIb/IV NSCLC who had not received prior chemotherapy was conducted to compare overall survival following treatment with pemetrexed plus cisplatin (AC) to gemcitabine plus cisplatin (GC). The median survival was 10.3 months in the AC arm and 10.3 months in the GC arm [adjusted hazard ratio 0.94 (95% CI: 0.84, 1.05)]. The median progression-free survival was 4.8 and 5.1 months for the AC and GC arms, respectively [adjusted hazard ratio 1.04 (95% CI: 0.94, 1.15)]. The overall response rates were 27.1% and 24.7% for the AC and GC arms, respectively.

A pre-specified analysis of the impact of NSCLC histology on overall survival was conducted in this trial. Clinically relevant differences in survival according to histology were observed. In the non-squamous cell NSCLC subgroup the median survival was 11.0 and 10.1 months in the AC and GC groups, respectively [unadjusted hazard ratio 0.84 (95% CI: 0.74, 0.96)]. However, in the squamous cell histology subgroup the median survival was 9.4 versus 10.8 months in the AC and GC groups, respectively [unadjusted hazard ratio 1.22 (95% CI: 0.99, 1.50)]. This unfavorable effect on overall survival associated with squamous cell histology observed with pemetrexed was also noted in a retrospective analysis of the single-agent trial of pemetrexed versus docetaxel in patients with stage III/ IV NSCLC after prior chemotherapy. Single-agent pemetrexed was approved in 2004 for this more heavily treated lung cancer population. Current product labeling has been revised to recommend that Alimta is also not indicated in patients with squamous cell lung cancer after prior chemotherapy.

The most common (>20%) adverse reactions in patients receiving pemetrexed plus cisplatin in NSCLC were nausea (56%), fatigue (43%), vomiting (40%), anemia (33%), neutropenia (29%), anorexia (27%), and constipation (21%).

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at <http://www.fda.gov/cder/foi/label/2008/021462s015lbl.pdf>