

## **ERLOTINIB WAS HIGHLY EFFECTIVE IN EAST ASIAN ADVANCED CHEMOTHERAPY–TREATED NON-SMALL CELL LUNG CANCER PATIENTS**

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**BACKGROUND:** Erlotinib (Tarceva<sup>®</sup>) is the first epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI) that demonstrated the survival benefit to chemotherapy-treated advanced stage non-small cell lung cancer (NSCLC) patients. An expanded access program (EAP) was designed to provide Erlotinib to NSCLC patients and to evaluate the efficacy and safety of Erlotinib in Taiwanese population.

**METHODS:** Patients with proven stage IIIB/IV NSCLC and received at least one regimen of standard systemic chemotherapy or radiation therapy were enrolled in this study. All patients were given oral erlotinib, 150 mg/d till disease progression or until intolerable toxicity occurred. Patient monitoring was done monthly, while tumor assessments were done every 2 months.

**RESULTS:** From April 2005 to February 2006, 293 patients were registered from 15 medical centers in Taiwan. The interim study evaluated the first 217 patients (54% male; median age 62 years [27 to 84]). Most patients had adenocarcinoma (65%) and squamous cell carcinoma (22%). 59% of patients receiving erlotinib as 2<sup>nd</sup>-line treatment. 58% of patients were currently smoking. The best response rate was 25% PR and 46% SD according to RECIST criteria (disease control rate=71%). The median time to progression was 24.0 weeks (95% CI, 18.7 to 32.0 weeks). Median overall survival was 39.7 weeks (95% CI, 33.7-NE). Seventeen percent of patients had dose reductions, mainly due to rash (65%) and diarrhea (24%).

**CONCLUSIONS:** This is the first report in the world demonstrating the superb response rates, time-to-progression and overall survival of erlotinib in a large population of East Asian advanced chemotherapy–treated NSCLC patients.

**Key words:** non-small cell lung cancer, erlotinib, epidermal growth factor receptor