Erlotinib tablets and EGFR mutation test, 7/13:104

The FDA has approved Roche Diagnostics' Tarceva (erlotinib) tablets for the initial treatment of people with metastatic non-small cell lung cancer (NSCLC) whose tumors have certain epidermal growth factor receptor (EGFR)-activating mutations as detected by an FDA-approved test. The FDA also approved Roche's Cobas EGFR mutation test.

In the United States, Tarceva is already approved, irrespective of histology or biomarker status, for people with advanced-stage NSCLC whose cancer has not spread or grown after initial treatment with certain types of chemotherapy. Tarceva is also approved for patients with advanced-stage NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen. Tarceva is not meant to be used at the same time as certain types of chemotherapy for advanced NSCLC. In Europe, Tarceva was approved in 2012 for the first-line treatment of NSCLC with EGFR-activating mutations.

This latest FDA approval for Tarceva is based on the results of the phase-three EURTAC study, which evaluated the first-line use of Tarceva versus platinum-based chemotherapy in people with EGFR-activating mutation-positive advanced NSCLC. Tumor shrinkage was observed in 65 percent of patients with Tarceva and in 16 percent of people treated with chemotherapy.

The Cobas EGFR mutation test is a real-time polymerase chain reaction-based diagnostic test for the qualitative detection and identification of exon 19 deletion or exon 21 (L858R) substitution mutations in the EGFR gene in DNA derived from formalin-fixed paraffin-embedded tumor tissue from NSCLC patients. The test is intended to be used to identify patients with advanced NSCLC whose tumors harbor these certain types of mutations.

***Roche Diagnostics**, 317-521-2000*