FDA approves Tarceva (erlotinib) tablets and cobas EGFR Mutation Test for specific type of lung cancer

Tarceva is the first personalised medicine approved for the initial treatment of people with EGFR mutation-positive metastatic non-small cell lung cancer in the United States

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Tarceva (erlotinib) tablets for the initial (first-line) treatment of people with metastatic non-small cell lung cancer (NSCLC) whose tumours have certain epidermal growth factor receptor (EGFR) activating mutations as detected by a FDA approved test. The FDA also approved the cobas EGFR Mutation Test, which was developed by Roche and validated in the pivotal EURTAC study. In the study, treatment with Tarceva demonstrated that patients lived longer without their disease getting worse (median progression-free survival; 10.4 months vs. 5.2 months; hazard ratio=0.34; p<0.001 [95% CI 0.23 to 0.49]) compared to chemotherapy. The safety profile for Tarceva in the EURTAC study was consistent with previous studies of Tarceva in NSCLC.

“Ten to 30 percent of people worldwide with lung cancer have tumours that test positive for certain EGFR mutations,” said Hal Barron, M.D., chief medical officer and head, Roche Global Product Development. “People with this type of lung cancer now have the option to use a personalised medicine as their initial treatment to help them live longer without their disease worsening.”

“Increasingly, doctors and patients rely on diagnostics to help guide personalised treatment decisions. The approval of the cobas EGFR Mutation Test highlights the importance of sensitive, accurate tests that can be conducted in time to inform crucial treatment decisions,” said Paul Brown, head of Roche Molecular Diagnostics. “At Roche, we have a deep commitment to providing personalised healthcare options and are currently developing companion diagnostics for more than half of the medicines in our pipeline.”

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 (maintenance treatment). Tarceva is also approved for patients with advanced-stage...
NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen (second- or third-line treatment). 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 III EURTAC study, which evaluated the first-line use of Tarceva versus platinum-based chemotherapy in people with EGFR-activating mutation-positive advanced NSCLC. Tumour shrinkage (response rate) was observed in 65 percent of patients with Tarceva and in 16 percent of people treated with chemotherapy. The most frequent (greater than or equal to 30 percent) adverse events in Tarceva-treated patients were diarrhea, weakness, rash, cough, shortness of breath and decreased appetite. The most frequent Grade 3-4 reactions in Tarceva-treated patients were rash and diarrhea.

About the EURTAC Study

- EURTAC (European Randomised Trial of Tarceva versus Chemotherapy) was designed and sponsored by the Spanish Lung Cancer Group (SLCG) and conducted in Spain, France and Italy in cooperation with Roche.
- The cobas EGFR Mutation Test was used to confirm people with mutations (exon 19 deletion or exon 21 [L858R] substitution) in the EGFR gene.
- From February 2007 to January 2011, 174 patients mostly of European descent were randomly assigned to receive Tarceva or platinum-based chemotherapy. The primary endpoint was investigator-assessed PFS.
- Randomization was stratified by certain EGFR mutations and ECOG performance status (0 vs. 1 vs. 2).
- The safety profile for Tarceva in the EURTAC study was consistent with previous studies of Tarceva in NSCLC.
- The most frequent (greater than or equal to 30 percent) adverse events in Tarceva-treated patients were diarrhea, weakness, rash, cough, shortness of breath and decreased appetite. The most frequent Grade 3-4 reactions in Tarceva-treated patients were rash and diarrhea.

About Lung Cancer

According to the American Cancer Society, it is estimated that more than 228,000 Americans will be diagnosed with lung cancer in 2013, and NSCLC accounts for 85 percent of all lung cancers. It is estimated that approximately 60 percent of lung cancer diagnoses are made when the disease is in the advanced stages.
About EGFR in Lung Cancer

EGFR is a protein that extends across the cell surface. Epidermal growth factor (EGF) binds to the part of the EGFR protein that sits on the outside of the cell. Binding leads to activation of the EGFR protein, which triggers a complex signalling cascade inside the cell that leads to events including accelerated cell growth and division and development of metastases (tumour growth and spread to other parts of the body). Some NSCLC tumours have activating mutations in the EGFR gene, changing the structure of the EGFR proteins such that they have increased activity.

About cobas EGFR Mutation Test

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 tumour (FFPET) tissue from NSCLC patients. The test is intended to be used to identify patients with metastatic NSCLC whose tumours harbour these certain types of mutations.

About Tarceva

Tarceva is a once-daily, oral non-chemotherapy medicine for the treatment of advanced or metastatic NSCLC. It has been shown to inhibit EGFR, a protein involved in the growth and development of cancers. Tarceva is developed and commercialised by Astellas Pharma U.S. in partnership with Genentech in the United States, Chugai in Japan and Roche in the rest of the world.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.
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