BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Astellas seeks FDA approval for Tarceva

23 November 2012 | News | By BioSpectrum Bureau

Astellas seeks approval of Traceva as first line treatment for non-small cell lung cancer

Singapore: Astellas Pharma US, a subsidiary of Tokyo-based Astellas Pharma, has submitted a supplemental new drug application (sNDA) to the US Food and Drug Administration (FDA) seeking approval for Tarceva (erlotinib) tablets. The application seeks approval of Tarceva use for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) activating mutations as detected by an approved test.

Tarceva is approved for patients with advanced 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 NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen (second-/third-line treatment).

The sNDA submission is based on results of the international EURTAC trial, a prospective, randomized, controlled phase III trial evaluating the first-line use of Tarceva versus platinumbased chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.

EGFR is a protein that extends across the cell membrane. The 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 signaling cascade inside the cell that leads to events including accelerated cell growth and division and development of metastases (tumor growth and spread to other parts of the body). Some NSCLC tumors have activating mutations in the EGFR gene, changing the structure of the EGFR proteins such that they have increased activity.

A companion diagnostic, the cobas EGFR Mutation Test, developed by Roche Molecular Diagnostics to identify people with NSCLC whose tumors have EGFR activating mutations, is currently under review by the Center for Devices and Radiological Health to support the EURTAC sNDA. It is estimated that as many as one in ten (10 percent) people in Western populations with lung cancer and three in ten (30 percent) Asian people with lung cancer have EGFR activating mutations.