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FDA accepts sNDA for Astellas cancer drug

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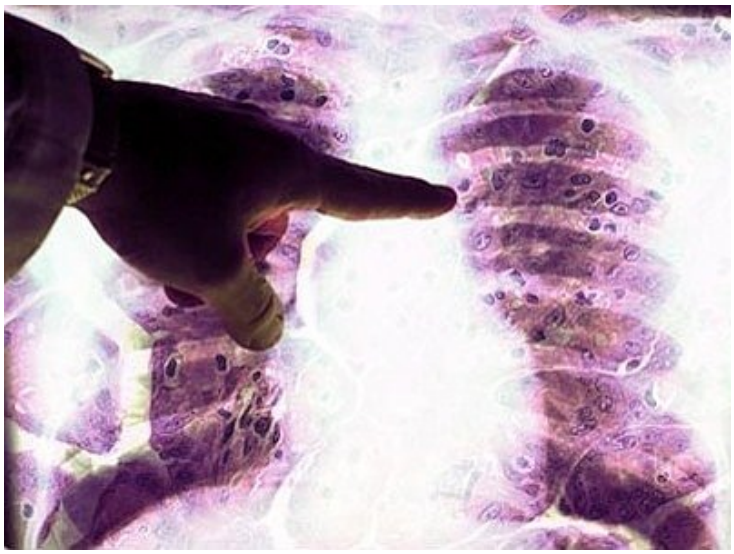

Singapore: The US FDA has accepted Astellas Pharma's US subsidiary filing of a supplemental New Drug Application (sNDA) for Tarceva (erlotinib) for first-line use in people with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) activating mutations.

The application has been granted Priority Review status, and an FDA decision is expected during the second quarter of 2013. A pre-market approval (PMA) application for a companion diagnostic, the cobas EGFR Mutation Test developed by Roche Molecular Diagnostics, has also been submitted to the FDA.

Dr stephen eck, vice president and head, medical oncology, global development, Astellas Pharma, said that, "We are pleased that the FDA granted an expedited six-month review of our application because lung cancer is one of the most common and deadly cancers."

He further added, "We are proud of Tarceva's already approved indications for the maintenance and relapsed advanced NSCLC settings. If approved, people with a genetically distinct form of lung cancer could have a potential new personalized medicine for use as a first-line treatment."

It is estimated that as many as one-in-ten lung cancer patient in western populations and three-in-ten lung cancer patients in Asian populations have EGFR activating mutations. 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 platinum-based chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.