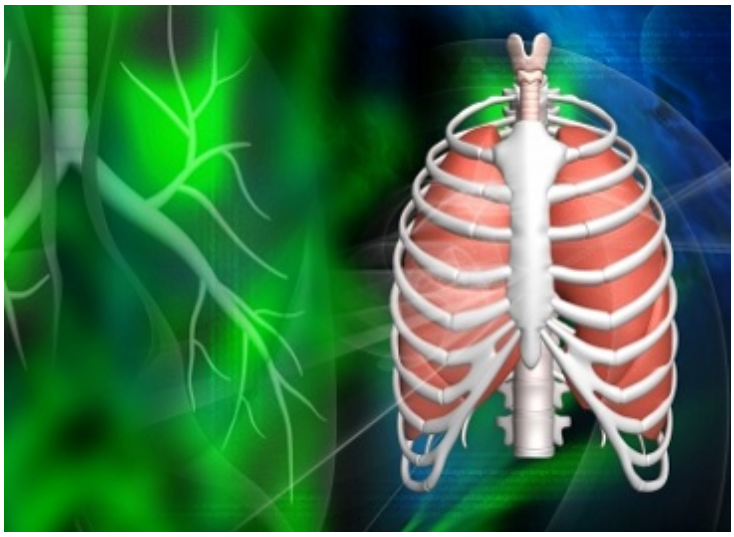
BioSpectrum the business of Bio & Health Sciences

FDA approves Roche's new lung cancer drug

15 December 2015 | News | By BioSpectrum Bureau

FDA approves Roche's new lung cancer drug



Roche has announced that the US Food and Drug Administration (FDA) granted accelerated approval to Alecensa (alectinib) for the treatment of people with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

In the pivotal studies, Alecensa shrank tumours in up to 44 percent of people with ALK-positive NSCLC who progressed on crizotinib (objective response rate [ORR] of 38 percent [95 percent CI 28-49] and 44 percent [95 percent CI 36-53]).

In a subset of people with tumours that spread to the brain or other parts of the central nervous system (CNS), Alecensa shrank CNS tumours in about 60 percent of people (CNS ORR of 61 percent [95 percent CI 46-74]).

"Alecensa is now approved as a new option for people with ALK-positive NSCLC who progress on or are intolerant to crizotinib," said Dr Sandra Horning, chief medical officer and head of global product development. "Sixty percent of people enrolled in our studies had tumours that had spread to their central nervous systems, and Alecensa shrank tumours in many people in a subset of patients with CNS disease."

Possible serious side effects with Alecensa include liver problems, lung problems, slow heartbeat, muscle pain, tenderness and weakness. The most common side effects of Alecensa include tiredness, constipation and swelling in the hands, feet, ankles and eyelids.

The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition based on early evidence suggesting clinical benefit. The indication for Alecensa is approved under accelerated approval based on tumour response rate and duration of response (DOR). Continued approval for this indication

may be contingent upon verification and description of clinical benefit in confirmatory trials.

In addition, Alecensa is being studied for use as an initial (first-line) treatment for people with advanced ALK-positive NSCLC. ALEX is a global, randomised phase III study comparing Alecensa to crizotinib as an initial treatment for people with advanced NSCLC whose tumours were characterized as ALK-positive by a companion VENTANA ALK (D5F3) CDx Assay immunohistochemistry (IHC) test developed by Roche Diagnostics.

This study is part of the company's commitment to convert the current accelerated approval in people with ALK-positive, metastatic NSCLC who have progressed on or are intolerant to crizotinib to a full approval as an initial treatment.