RXADVANCE
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Alunbrig (brigatinib) Tablets
Clinical Update

Clinical Update: FDA Approved Alunbrig (brigatinib) as a First-Line Treatment Option for Patients with ALK+ Metastatic Non-Small Cell Lung Cancer (NSCLC).
FDA approval date: May 22, 2020

Alunbrig (brigatinib) is a potent and selective next-generation tyrosine kinase inhibitor (TKI) that was designed to target anaplastic lymphoma kinase (ALK) molecular alterations. Alunbrig indicated for the treatment of patient with ALK+ metastatic NSCLC who have taken the medicine crizotinib, but their NSCLC has worsened or they cannot tolerate taking crizotinib. Alunbrig is also approved in the EU as a monotherapy for the treatment of adult patients with ALK+ advanced NSCLC previously not treated with an ALK inhibitor.

Takeda Pharmaceutical's Alunbrig (brigatinib) has been approved in the US as a First-Line Treatment Option for Patients with ALK+ Metastatic Non-Small Cell Lung Cancer (NSCLC). The approval by the US Food and Drug Administration (FDA) was based on results from the Phase 3 ALTA 1L trial, which is evaluating the safety and efficacy of Alunbrig compared to crizotinib in adult patients with ALK+ locally advanced or metastatic NSCLC who have not received prior treatment with an ALK inhibitor. Blinded independent review committee (BIRC)-assessed progression-free survival (PFS) was the major efficacy outcome measure. Additional efficacy outcome measures included confirmed overall response rate (ORR) per RECIST v1.1 and intracranial ORR.

The warnings and precautions for Alunbrig are: interstitial lung disease (ILD)/pneumonitis, hypertension, bradycardia, visual disturbance, creatine phosphokinase (CPK) elevation, pancreatic enzyme elevation, hyperglycemia and embryo-fetal toxicity.