Alunbrig® (brigatinib) – Expanded indication

- On May 22, 2020, Takeda announced the FDA approval of Alunbrig (brigatinib), for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.
    - Alunbrig was previously approved for the treatment of patients with ALK-positive metastatic NSCLC who have progressed on or are intolerant to Xalkori® (crizotinib).
- This approval expands Alunbrig's indication to include the first-line setting.
- The approval of Alunbrig for the expanded indication was based on the ALTA 1L trial, a randomized, open-label study in 275 adult patients with advanced ALK-positive NSCLC who had not previously received an ALK-targeted therapy. Patients were randomized to receive Alunbrig or Xalkori. The major efficacy outcome measure was progression-free survival (PFS) and additional efficacy outcome measures included confirmed overall response rate (ORR) and duration of response (DOR).
    - Median PFS was 24.0 months vs. 11.0 months for Alunbrig and Xalkori, respectively (hazard ratio [HR] 0.49; 95% CI: 0.35, 0.68; $p < 0.0001$).
    - The confirmed ORR was 74% (95% CI: 66, 81) for Alunbrig vs. 62% (95% CI: 53, 70) for Xalkori ($p = 0.0342$).
    - The median DOR was not reached (95% CI: 19.4, not estimable) for Alunbrig and 13.8 months (95% CI: 9.3, 20.8) for Xalkori.
- The recommended dose of Alunbrig is 90 mg orally once daily for the first 7 days; then the dose should be increased to 180 mg orally once daily. Alunbrig should be administered until disease progression or unacceptable toxicity.
    - Patients should be selected for the treatment based on the presence of ALK positivity in tumor specimens. Information on FDA-approved tests for the detection of ALK rearrangements in NSCLC is available at http://www.fda.gov/CompanionDiagnostics.