Alecensa® (alectinib) – New indication

- On April 18, 2024, Genentech announced the FDA approval of Alecensa (alectinib), as adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.

- Alecensa is also approved for the treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test.

- The approval of Alecensa for the new indication was based on a randomized, open-label study in 257 patients with resectable ALK-positive NSCLC. Patients were randomized to receive Alecensa or platinum-based chemotherapy following tumor resection. The major efficacy measures were disease-free survival (DFS) in patients with stage II-IIIA NSCLC and DFS in patients with stage IB-IIIA NSCLC (intent-to-treat [ITT] population).

    — In the stage II-IIIA population, median DFS was not reached with Alecensa vs. 44.4 months with chemotherapy (hazard ratio [HR] 0.24, 95% CI: 0.13, 0.45; $p < 0.0001$). In the ITT population, median DFS was not reached with Alecensa vs. 41.3 months with chemotherapy (HR 0.24, 95% CI: 0.13, 0.43; $p < 0.0001$).

- The recommended dose of Alecensa for both of its uses is 600 mg orally twice daily. The duration of treatment for adjuvant treatment of resected NSCLC is a total of 2 years or until disease recurrence or unacceptable toxicity.

    — Refer to the Alecensa drug label for complete dosing recommendations.