Alunbrig™ (brigatinib) – New orphan drug approval

- On April 28, 2017, the FDA announced the approval of Ariad's Alunbrig (brigatinib) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori® (crizotinib).

- According to the American Cancer Society, NSCLC is the most common type of lung cancer, accounting for about 85% of lung cancers. In the U.S., it is estimated there will be about 222,500 new cases and about 155,870 deaths from lung cancer in 2017.

- Alunbrig is a tyrosine kinase inhibitor (TKI). TKIs work by specifically targeting cancer cells.

- The efficacy of Alunbrig was demonstrated in the open-label ALTA trial of 222 patients with locally advanced or metastatic ALK-positive NSCLC. Patients received Alunbrig 90 mg daily or Alunbrig 90 mg daily for 7 days, then 180 mg daily. The major efficacy outcome measure was overall response rate (ORR).

    — For patients who received 90 mg daily, the ORR was 48% (95% CI: 39, 58). The ORR for patients who received 90 mg daily for 7 days, then 180 mg daily was 53% (95% CI, 43, 62).
    — The duration of response for the 90 mg group was 13.8 months (95% CI: 7.4, not estimable [NE]) and for the 90 mg to 180 mg group, 13.8 months (95% CI: 9.3, NE).

- Warnings and precautions of Alunbrig include interstitial lung disease, pneumonitis, hypertension, bradycardia, visual disturbance, creatine phosphokinase elevation, pancreatic enzyme elevation, hyperglycemia, and embryo-fetal toxicity.

- The most common adverse reactions (≥ 25%) with Alunbrig use were nausea, diarrhea, fatigue, cough, and headache.

- The recommended dose of Alunbrig is 90 mg orally once daily for the first 7 days; if 90 mg is tolerated during the first 7 days, increase the dose to 180 mg orally once daily.

- Ariad Pharmaceuticals plans to launch Alunbrig in mid May 2017. Alunbrig will be available as 30 mg and 90 mg film-coated tablets.