

## Alunbrig<sup>™</sup> (brigatinib) – New orphan drug approval

- On April 28, 2017, the <u>FDA announced</u> the approval of <u>Ariad's Alunbrig (brigatinib)</u> 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 <u>Xalkori® (crizotinib)</u>.
- According to the <u>American Cancer Society</u>, 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.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.