

## Xalkori® (crizotinib) - New indication

- On July 14, 2022, the FDA approved Pfizer's <u>Xalkori (crizotinib)</u>, for the treatment of adult and
  pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory
  myofibroblastic tumor (IMT) that is anaplastic lymphoma kinase (ALK)-positive.
- Xalkori is also approved for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ALK or ROS1-positive as detected by an FDA-approved test and for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.
- The approval of Xalkori for the new indication in pediatric patients was based on ADVL0912, a single-arm, open-label study in patients 1 to ≤ 21 years of age that included 14 pediatric patients with unresectable, recurrent, or refractory ALK-positive IMT. The major efficacy outcome was objective response rate (ORR) in pediatric patients.
  - The ORR was 86% (95% CI: 57, 98).
- The approval of Xalkori for the new indication in adult patients was based on A8081013, a singlearm, open-label study that included 7 adult patients with unresectable, recurrent, or refractory ALK-positive IMT. The major efficacy outcome was ORR.
  - For the 7 patients with ALK-positive IMT, 5 experienced a response including 1 complete response.
- The most common adverse reactions (≥ 35%) with Xalkori use in adult patients with IMT were vision disorders, nausea, and edema.
- The most common adverse reactions (≥ 35%) with Xalkori use in pediatric patients with IMT were vomiting, nausea, diarrhea, abdominal pain, rash, vision disorder, upper respiratory tract infection, cough, pyrexia, musculoskeletal pain, fatigue, edema, constipation, and headache.
- The recommended dose of Xalkori for the treatment of IMT is 250 mg orally twice daily in adults and 280 mg/m² orally twice daily in pediatric patients.
  - Refer to the Xalkori drug label for dosing for its other indications.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.