Xalkori® (crizotinib) – New indication

- On July 14, 2022, the FDA approved Pfizer's Xalkori (crizotinib), 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 single-arm, 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/m^2 orally twice daily in pediatric patients.

    — Refer to the Xalkori drug label for dosing for its other indications.