Xalkori® (crizotinib) – New formulation approval

- On September 7, 2023, the FDA approved a new oral pellet formulation of Pfizer's Xalkori (crizotinib).
    - Xalkori was previously approved as an oral capsule.
- Xalkori is approved for the treatment of:
    - Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test
    - 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
    - Adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is ALK-positive.
- Xalkori oral pellets are administered twice daily by one of two options:
    - Open shell(s) containing Xalkori pellets and empty the contents directly into the patient's mouth
    - Open shell(s) containing Xalkori pellets and empty the contents into a consumer -supplied oral dosing aid (eg, spoon, medicine cup). Xalkori pellets should be administered via the dosing aid directly into the patient's mouth.
- Refer to the Xalkori drug label for complete dosing and administration recommendations for oral capsules and pellets.
- Pfizer's launch plans for Xalkori oral pellets are pending. Xalkori oral pellets will be available in 20 mg, 50 mg, and 150 mg strengths.