Retevmo® (selpercatinib) – New formulation approval

- On April 10, 2024, the FDA approved a new oral tablet formulation of Eli Lilly's Retevmo (selpercatinib).
    - Retevmo was previously approved as an oral capsule.
- Retevmo is approved for the treatment of:
    - Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test.
    - Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy.
    - Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
    - Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- Warnings and precautions for Retevmo include hepatotoxicity; interstitial lung disease/pneumonitis; hypertension; QT interval prolongation; hemorrhagic events; hypersensitivity; tumor lysis syndrome; risk of impaired wound healing; hypothyroidism; and embryo-fetal toxicity.
- The recommended dosage of Retevmo, based on body weight, is:
    - Less than 50 kg: 120 mg taken orally twice daily with or without food
    - 50 kg or greater: 160 mg taken orally twice daily with or without food
    - Treatment with Retevmo should be continued until disease progression or unacceptable toxicity.
- Eli Lilly's launch plans for Retevmo tablets are pending. Retevmo tablets will be available as a 40 mg, 80 mg, 120 mg, and 160 mg strength.