Retevmo® (selpercatinib) – Expanded indications

- On May 29, 2024, the FDA approved Eli Lilly's Retevmo (selpercatinib), for the treatment of adult and pediatric patients 2 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.
    - 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)
    - Locally advanced or metastatic solid tumors with a RET gene fusion, as detected by an FDA-approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

- Retevmo was previously approved for MTC and thyroid cancer in patients 12 years of age and older and for solid tumors in adults only. This approval expanded the population to patients 2 years of age and older for these indications.

- Retevmo is also approved for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a RET gene fusion, as detected by an FDA-approved test.

- The approval of Retevmo for the expanded indications was based on LIBRETTO-121, an open-label, multi-cohort study in pediatric and young adult patients with advanced RET-activated solid tumors. Efficacy was evaluated in 10 patients with RET fusion-positive thyroid cancer and 14 patients with RET-mutant MTC, respectively, who were non-responsive to available therapies or had no standard systemic curative therapy available.
    - In RET fusion-positive thyroid cancer, the overall response rate (ORR) was 60% (95% CI: 26, 88). The median duration of response (DOR) was not reached (95% CI: not estimable, not estimable).
    - In RET-mutant MTC, the ORR was 43% (95% CI: 18, 71). The median DOR was not reached (95% CI: not estimable, not estimable).

- The most common adverse reactions (≥ 25%) in pediatric patients with solid tumors were musculoskeletal pain, diarrhea, headache, nausea, vomiting, coronavirus infection, abdominal pain, fatigue, pyrexia, and hemorrhage.

- The most common Grade 3 or 4 laboratory abnormalities (≥ 5%) in pediatric patients with solid tumors were decreased calcium, decreased hemoglobin, and decreased neutrophils.

- The recommended dose of Retevmo for the treatment of pediatric patients 2 to less than 12 years of age is based on body surface area and given orally:
    - 0.33 to 0.65 m^2: 40 mg three times daily
    - 0.66 to 1.08 m^2: 80 mg twice daily
    - 1.09 to 1.52 m^2: 120 mg twice daily
    - ≥ 1.53 m^2: 160 mg twice daily

- Treatment should be continued until disease progression or unacceptable toxicity.

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- Refer to the Retevmo drug label for dosing for adult and adolescent patients 12 years of age.