Tukysa® (tucatinib) – New indication

- On January 19, 2023, Seagen announced the FDA approval of Tukysa (tucatinib), in combination with trastuzumab, for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Tukysa is also approved, in combination with trastuzumab and capecitabine, for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- In the U.S., approximately 153,000 people will be diagnosed with colorectal cancer in 2023. Approximately 22% of patients with colorectal cancer are diagnosed at the advanced stage.
    - HER2 is overexpressed in 3% to 5% of patients with metastatic colorectal cancer and approximately 10% of patients with RAS wild-type metastatic colorectal cancer.
- The approval of Tukysa for the new indication was based on MOUNTAINEER, an open-label study in 84 patients with HER2-positive, RAS wild-type, unresectable or metastatic colorectal cancer following previous standard-of-care therapies. Patients received Tukysa with trastuzumab or a non-U.S. approved trastuzumab product until disease progression or unacceptable toxicity. The major outcome measures were overall response rate (ORR) and duration of response (DOR).
    - The ORR was 38% (95% CI: 28, 49).
    - The median DOR was 12.4 months (95% CI: 8.5, 20.5).
- The most common adverse reactions (≥ 20%) with Tukysa use in combination with trastuzumab in patients with unresectable or metastatic colorectal cancer were diarrhea, fatigue, rash, nausea, abdominal pain, infusion related reactions, and pyrexia.
- The recommended dosage of Tukysa is 300 mg taken orally twice daily in combination with trastuzumab until disease progression or unacceptable toxicity.
- Refer to the Tukysa drug label for dosing recommendations for breast cancer.