Truseltiq™ (infigratinib) – New drug approval

- On May 28, 2021, BridgeBio Pharma, through its affiliate QED Therapeutics, and Helsinn Group announced the FDA approval of Truseltiq (infigratinib), for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
    - This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Cholangiocarcinoma is a cancer of the bile ducts of the liver. FGFR2 genetic aberrations are present in approximately 15% to 20% of people who have this disease. Currently, the 5-year survival rate is only 9%.
- Truseltiq is a tyrosine kinase inhibitor of FGFR.
- The efficacy of Truseltiq was established in an open-label, single-arm study in 108 patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement. The major efficacy outcome measures were ORR and DOR.
    - The ORR was 23% (95% CI: 16, 32).
    - The median DOR was 5.0 months (95 CI%: 3.7, 9.3).
- Warnings and precautions for Truseltiq include ocular toxicity, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Truseltiq use were nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodysesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred and vomiting.
- The most common laboratory abnormalities (≥ 20%) with Truseltiq use were increased creatinine, increased phosphate, decreased phosphate, increased alkaline phosphatase, decreased hemoglobin, increased alanine aminotransferase, increased lipase, increased calcium, decreased lymphocytes, decreased sodium, increased triglycerides, increased aspartate aminotransferase, increased urate, decreased platelets, decreased leukocytes, decreased albumin, increased bilirubin and decreased potassium.
- The recommended dosage of Truseltiq is 125 mg (one 100 mg capsule and one 25 mg capsule) orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles. Treatment should be continued until disease progression or unacceptable toxicity.
    - Patients should be selected for the treatment based on the presence of an FGFR2 fusion or rearrangement, as detected by an FDA-approved test.
    - Information on FDA-approved test(s) for the detection of FGFR2 fusions or rearrangements in cholangiocarcinoma is available at: http://www.fda.gov/CompanionDiagnostics.

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- BridgeBio's launch plans for Truseltiq are pending. Truseltiq will be available as a 25 mg and 100 mg capsule.

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