Romvimza™ (vimseltinib) – New drug approval

- On February 14, 2025, Ono Pharmaceutical's announced the FDA approval of Romvimza (vimseltinib), for **treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity**.

- TGCT is a rare, non-malignant tumor that forms within or near joints. TGCT arises from the dysregulation of the colony-stimulating factor 1 (CSF1) gene, resulting in an overproduction of CSF1.

- Romvimza is a kinase inhibitor that inhibits CSF1 receptor (CSF1R).

- The efficacy of Romvimza was established in MOTION, a randomized, double-blind, placebo-controlled study in 123 patients with TGCT for whom surgical resection may cause worsening functional limitation or severe morbidity. Patients were randomized to placebo or Romvimza for 24 weeks. The major outcome measure was overall response rate (ORR).

    — The ORR was 40% (95% CI: 29, 51) for Romvimza and 0% (95% CI: 0, 9) for placebo ($p < 0.0001$).

- Warnings and precautions for Romvimza include hepatotoxicity, embryo-fetal toxicity, allergic reactions to FD&C Yellow No.5 (tartrazine) and No. 6 (Sunset Yellow FCF), and increased creatinine without affecting renal function.

- The most common adverse reactions (≥ 20%), including laboratory abnormalities, with Romvimza use were increased aspartate aminotransferase, periorbital edema, fatigue, rash, increased cholesterol, peripheral edema, face edema, decreased neutrophils, decreased leukocytes, pruritus, and increased alanine aminotransferase.

- The recommended dose of Romvimza is **30 mg orally taken twice weekly**, with a minimum of 72 hours between doses, as directed on the blister package. Patients should follow the schedule on the blister package and take Romvimza on the same days each week.

- Ono Pharmaceutical plans to launch Romvimza in the next week. Romvimza will be available as a 14 mg, 20 mg, and 30 mg capsule.