Mulpleta® (lusutrombopag) – New drug approval

- On July 31, 2018, Shionogi announced the FDA approval of Mulpleta (lusutrombopag), for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

- Thrombocytopenia is a common complication of CLD, which may be caused by multiple factors including decreased production of thrombopoietin (TPO). Patients with CLD and thrombocytopenia are at increased risk for bleeding, requiring recurrent platelet transfusions, increased ambulatory visits and inpatient hospital stays.

- Mulpleta is a small molecule TPO receptor agonist that induces the proliferation and differentiation of progenitor cells from hematopoietic stem cells and megakaryocyte maturation.

- The efficacy of Mulpleta for the treatment of thrombocytopenia in patients with CLD who are scheduled to undergo a procedure was evaluated in two placebo-controlled trials enrolling 312 patients. In the first study, the major efficacy outcome was the proportion of patients who require no platelet transfusion prior to the primary invasive procedure. In the second study, the major efficacy outcome was the proportion of patients who require no platelet transfusion prior to the primary invasive procedure and no rescue therapy for bleeding.

    — In the first study, 78% of Mulpleta-treated patients met the primary efficacy outcome vs. 13% of placebo-treated patients (treatment difference = 64 [95% CI: 49, 79]; $p < 0.0001$).
    — In the second study, 65% of Mulpleta-treated patients met the primary efficacy outcome vs. 29% of placebo-treated patients (treatment difference = 37 [95% CI: 25, 49]; $p < 0.0001$).

- Warning and precautions of Mulpleta include thrombotic/thromboembolic complications.

- The most common adverse reaction (≥ 3%) with Mulpleta use was headache.

- The recommended dosage of Mulpleta is 3 mg orally once daily with or without food for 7 days.

    — Begin Mulpleta dosing 8 - 14 days prior to a scheduled procedure.
    — Patients should undergo their procedure 2 - 8 days after the last dose.
    — Obtain a platelet count prior to initiation of Mulpleta therapy and not more than 2 days before the procedure.
    — Mulpleta should not be administered to patients with CLD in an attempt to normalize platelet counts.

- Shionogi plans to launch Mulpleta in early September of 2018. Mulpleta will be available as 3 mg tablets.