Doptelet® (avatrombopag) – New drug approval

- On May 21, 2018, the FDA announced the approval of Dova Pharmaceuticals' Doptelet (avatrombopag) for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

- Thrombocytopenia, a reduction in the number of platelets in the blood, is a common complication in patients with CLD. Thrombopoietin (TPO) is made in the liver and stimulates bone marrow production of platelets, which are critical blood components for controlling bleeding. As a result of damage to the liver in patients with CLD, TPO production is reduced, which consequently results in decreased platelet production.

    - There are approximately 70,000 patients with CLD that have thrombocytopenia. If not effectively treated, thrombocytopenia can lead to serious uncontrolled bleeding, resulting in prolonged hospitalizations and other post-procedure complications.

- Doptelet is a thrombopoietin (TPO) receptor agonist. Doptelet is designed to mimic the effects of TPO, the primary regulator of normal platelet production.

- The safety and efficacy of Doptelet were based on two placebo-controlled trials involving 435 patients with chronic liver disease and severe thrombocytopenia who were scheduled to undergo a procedure that would typically require platelet transfusion. The primary efficacy endpoint was the proportion of patients not requiring platelet transfusion or any rescue procedure for bleeding up to 7 days following the elective procedure.

    - In both trials, statistically greater proportions of Doptelet-treated patients achieved the primary endpoint vs. placebo-treated patients.

- Warnings and precaution of Doptelet includes thrombotic/thromboembolic complications.

- The most common adverse reactions (≥ 3%) with Doptelet use were pyrexia, abdominal pain, nausea, headache, fatigue, and peripheral edema.

- The recommended dose of Doptelet is based on the patient's platelet count prior to the scheduled procedure, and should be taken orally once daily for 5 consecutive days.

    - Doptelet should be started 10 – 13 days prior to the scheduled procedure, and patients should undergo their procedure 5 – 8 days after the last dose of Doptelet.
    - Doptelet should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.
    - Refer to the Doptelet drug label for further information.

- Dova Pharmaceuticals plans to launch Doptelet in June of 2018. Doptelet will be available as 20 mg tablets