Doptelet® (avatrombopag) – New indication

- On June 27, 2019, Dova Pharmaceuticals announced the FDA approval of Doptelet (avatrombopag), for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

- Doptelet is also approved for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

- ITP is a rare autoimmune bleeding disorder that affects approximately 60,000 adults in the U.S. It is characterized by low numbers of platelets that lead to excessive bruising and severe bleeding. ITP is considered chronic when symptoms last more than 12 months.

- The approval of Doptelet for the new indication was based on a double-blind study in 49 adult patients with chronic ITP. Patients were randomized to receive either Doptelet or placebo. The major efficacy outcome in this study was the cumulative number of weeks in which the platelet count was ≥ 50 $x10^9$/L during the 6-month treatment period in the absence of rescue therapy.

    — Doptelet-treated patients had a longer duration of platelet counts ≥ 50 $x10^9$/L in the absence of rescue therapy vs. those who received placebo (median 12.4 [0, 25] vs 0 [0, 2] weeks, respectively, $p < 0.0001$).

- The most common adverse reactions (≥ 10%) with Doptelet use in patients with chronic ITP were headache, fatigue, contusion, epistaxis, upper respiratory tract infection, arthralgia, gingival bleeding, petechiae and nasopharyngitis.

- The recommended starting dose of Doptelet for chronic ITP is 20 mg (1 tablet) once daily with food. The dose or frequency of dosing should be adjusted to maintain platelet counts ≥ 50 $x10^9$/L. The dose should not exceed a daily dose of 40 mg (2 tablets).

    — Refer to the Doptelet drug label for dosing for its other indication.