

## Doptelet® (avatrombopag) - New drug approval

- On May 21, 2018, the <u>FDA announced</u> the approval of <u>Dova Pharmaceuticals' Doptelet</u>
   (<u>avatrombopag</u>) 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, fatique, 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



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