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May 21, 2018 – The U.S. Food and Drug Administration today approved Doptelet (avatrombopag) tablets to treat low blood platelet count (thrombocytopenia) in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. This is the first drug approved by the FDA for this use.

“Patients with chronic liver disease who have low platelet counts and require a procedure are at increased risk of bleeding,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “Doptelet was demonstrated to safely increase the platelet count. This drug may decrease or eliminate the need for platelet transfusions, which are associated with risk of infection and other adverse reactions.”

Platelets (thrombocytes) are colorless cells produced in the bone marrow that help form blood clots in the vascular system and prevent bleeding. Thrombocytopenia is a condition in which there is a lower-than-normal number of circulating platelets

in the blood. When patients have moderately to severely reduced platelet counts, serious or life-threatening bleeding can occur, especially during invasive procedures. Patients with significant thrombocytopenia typically receive platelet transfusions immediately prior to a procedure to increase the platelet count.

The safety and efficacy of Doptelet was studied in two trials (ADAPT-1 and ADAPT-2) involving 435 patients with chronic liver disease and severe thrombocytopenia who were scheduled to undergo a procedure that would typically require platelet transfusion. The trials investigated two dose levels of Doptelet administered orally over five days as compared to placebo (no treatment). The trial results showed that for both dose levels of Doptelet, a higher proportion of patients had increased platelet counts and did not require platelet transfusion or any rescue therapy on the day of the procedure and up to seven days following the procedure as compared to those treated with placebo.

The most common side effects reported by clinical trial participants who received Doptelet were fever, stomach (abdominal) pain, nausea, headache, fatigue and swelling in the hands or feet (edema). People with chronic liver disease and people with certain blood clotting conditions may have an increased risk of developing blood clots when taking Doptelet.

This product was granted Priority Review, under which the FDA’s goal is to take action on an application within six months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

The FDA granted this approval to AkaRx Inc.

Source: FDA

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