

New Drug Approvals

Generic Name (Trade Name—Company)

August 1, 2018

Lusutrombopag

(Mulpleta—Shionogi)

New drug targets thrombocytopenia in adults with chronic liver disease

Uses/Notes

FDA [approved](#) lusutrombopag, a once-daily, orally administered, small molecule thrombopoietin receptor agonist, for treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure.

Approval was based on two randomized, double-blind, placebo-controlled trials involving 312 patients with chronic liver disease and severe thrombocytopenia who were undergoing an invasive procedure and had a platelet count of less than 50 x 10⁹/L. Patients were randomized 1:1 to receive 3 mg of lusutrombopag or placebo once daily for up to 7 days.

In one trial, 78% of patients (38/49) receiving lusutrombopag required no platelet transfusion prior to the primary invasive procedure, compared with 13% (6/48) who received placebo. In the second trial, 65% (70/108) of patients who received lusutrombopag required no platelet transfusion prior to the primary invasive procedure or rescue therapy for bleeding from randomization through 7 days after the procedure, compared with 29% (31/107) receiving placebo.

The most common adverse reaction (?3% of patients) was headache.

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

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