Patients Treated With Mulpleta Achieved a Platelet Count of ≥50,000/μL and Had a Minimum Increase of 20,000/μL From Baseline

In two clinical trials, 76% (37/49) and 65% (70/108) of patients treated with Mulpleta achieved a platelet count of ≥50,000/μL and had a minimum increase of 20,000/μL from baseline.

Patients undergoing laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection were excluded from clinical trials. Patients with a history of splenectomy, partial splenic embolization, or thrombosis and those with Child-Pugh class C liver disease, absence of hepatopetal blood flow, or a prothrombotic condition other than chronic liver disease were also not allowed to participate.

Important Safety Information

Warnings and Precautions: Mulpleta is a thrombopoietin (TPO) receptor agonist, and TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Portal vein thrombosis has been reported in patients with chronic liver disease treated with TPO receptor agonists. Portal vein thrombosis was reported in 1% of Mulpleta-treated patients and 1% of placebo-treated patients.

Consider the potential increased thrombotic risk when administering Mulpleta to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions (Factor V Leiden, Prothrombin 20210A, Antithrombin deficiency, or Protein C or S deficiency). Monitor platelet counts and for thromboembolic events and institute treatment promptly.

Mulpleta should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts.

Adverse Reactions: The most common adverse reaction (≥3%) with Mulpleta was headache.

To report suspected Adverse Reactions, contact Shionogi at 1-800-849-9707 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see a Brief Summary of Prescribing Information on next page.