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Shionogi's thrombocytopenia drug receives 'priority review' designation by the US FDA

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Japan's Shionogi has announced that the New Drug Application (NDA) for lusutrombopag (S-888711) -an investigational candidate has been accepted for filing and has been granted Priority Review by the U.S. Food & Drug Administration (FDA).

Lusutrombopag is developed for the treatment of thrombocytopenia in patients with chronic liver disease who are at increased risk for bleeding associated with invasive procedures.

Lusutrombopag has already bagged the Japanese approval in September 2015 for the improvement of thrombocytopenia associated with chronic liver disease (CLD) in patients undergoing an elective invasive procedure.

Thrombocytopenia is frequently observed in patients with CLD, with studies suggesting that it occurs in up to 78% of patients with cirrhosis.1 CLD-associated thrombocytopenia is defined as a platelet count of less than 150,000/µL and is the most common hematologic complication of CLD

The submission is based on two Phase 3 clinical trials, L-PLUS1 and L-PLUS2, in which lusutrombopag met the pre-specified primary and all key secondary endpoints with statistically significant results. The Prescription Drug User Fee Act (PDUFA) date for an FDA decision is August 26, 2018.

"I am very pleased the FDA has granted Priority Review for lusutrombopag's New Drug Application. This step emphasizes an urgent need exists for more advanced medicines for the treatment of thrombocytopenia in patients living with chronic liver disease (CLD) who have to undergo invasive procedures," said John Keller, President and Chief Executive Officer, Shionogi Inc. "We at Shionogi look forward to the upcoming FDA review, and the near future in which patients and physicians have additional, advanced therapeutic options beyond platelet transfusions which are the current standard of care."

The FDA Priority Review status accelerates the review time from a standard 10-month review to a goal of six months from the date of acceptance of filing. A Priority Review designation will direct overall attention and resources to the evaluation of applications that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

The European Medicines Agency has validated for review Shionogi's standard Marketing Authorization Application (MAA) for lusutrombopag. In Europe, the MAA submission is based on the same two Phase 3 clinical trials as the FDA filing.