

Shionogi Receives Marketing and Manufacturing Approval in Japan for MULPLETA[®] Tablets 3mg for Improvement of Thrombocytopenia

Osaka, Japan, September 28, 2015 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced the receipt of marketing and manufacturing approval in Japan for MULPLETA[®] Tablets 3mg, indicated for the improvement of thrombocytopenia associated with chronic liver disease in patients undergoing an elective invasive procedure. Shionogi will launch the product immediately after the National Health Insurance (NHI) price listing.

Thrombocytopenia is a frequent occurrence in patients with chronic liver disease. In order to reduce the risk of bleeding in such patients who are undergoing elective invasive procedures, steps are taken to increase platelet counts prior to the procedure. Historically, the most common approach has been platelet transfusion or the administration of platelet products; however, these are associated with certain risks. Therefore, a medical need exists for simple and well tolerated therapeutic alternatives to platelet transfusion.

MULPLETA[®] is a small molecule thrombopoietin (TPO) receptor agonist discovered and developed by Shionogi, which induces the proliferation and differentiation of human bone marrow progenitor cells into megakaryocytes, consequently increasing platelet levels. In the Japanese phase III studies, MULPLETA[®] (3 mg of lusutrombopag once daily for 7 days) significantly increased the proportion of patients who did not require platelet transfusion prior to invasive procedures compared to the placebo group. MULPLETA[®] is much more effective, and results in a longer-lasting effect, than platelet transfusion.

MULPLETA[®] is expected to become an alternative to platelet transfusion for patients with chronic liver disease in order to increase platelet levels prior to elective invasive procedures. Japan is the first country to approve MULPLETA[®], and MULPLETA[®] is the first TPO receptor agonist approved for this indication anywhere in the world.

Shionogi will strive to achieve its mission to "supply the best possible medicine to protect the health and wellbeing of the patients we serve" and thereby to improve the quality of life for patients all over the world as a drug-discovery-based pharmaceutical company.

Product Overview

Product Name:	MULPLETA [®] Tablets 3mg
Generic Name:	lusutrombopag
Indication:	Improvement of thrombocytopenia associated with chronic liver disease in patients prior to elective invasive procedures
Dosage and Administration:	3 mg of lusutrombopag once daily orally for 7 days for adult patients.
Approval Date:	September 28, 2015

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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