Press Release

SHIONOGI TO PRESENT CLINICAL DATA ON LUSUTROMBOPAG AT THE INTERNATIONAL LIVER CONGRESS™ 2019 OF THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER (EASL)

OSAKA, Japan, and AMSTERDAM, NL - April 4, 2019 - Shionogi & Co., Ltd. and its European subsidiary, Shionogi B.V. (hereafter "Shionogi"), announced it will present four posters on lusutrombopag, a once-daily, orally administered, small molecule thrombopoietin (TPO) receptor agonist, at The International Liver Congress™, the annual meeting of the European Association for the Study of the Liver (EASL), to be held in Vienna, Austria, April 10-14, 2019. Lusutrombopag was granted marketing authorisation by the European Commission (EC) on February 18, 2019 for the treatment of severe thrombocytopenia in adult patients with chronic liver disease (CLD) undergoing invasive procedures. It has already been approved for use in Japan[1] and the US where it is marketed under the brand name Mulpleta®[2].

All poster presentations will be displayed in Reed Messe Wien Exhibition & Congress Center Hall B on Saturday, April 13, 2019 from 9:00 am to 5:00 pm Central European Time (CET). The research will be presented in the Cirrhosis and Complications poster area and will include the following:

- Poster SAT 002: Lusutrombopag Is a Safe Treatment Option for Thrombocytopenia in Patients with Chronic Liver Disease Undergoing an Invasive Procedure: Pooled Safety Analysis from 3 Studies

  Presenter: Nezam Afdhal

- Poster SAT 003: Real-World Data Demonstrate Safety and Effectiveness of Lusutrombopag in Chronic Liver Disease Patients with Thrombocytopenia Undergoing Planned Invasive Procedures: Interim Analysis

  Presenter: Nezam Afdhal

- Poster SAT 006: Efficacy of Oral Thrombopoietin Receptor Agonist Lusutrombopag in Chronic Liver Disease by Underlying Disease Aetiology

  Presenter: Naim Alkhouri

- Poster SAT 038: Lusutrombopag for Treatment of Thrombocytopenia in Patients with Chronic Liver Disease Who Are Undergoing Planned Invasive Procedures: Pooled Safety Analysis of Bleeding-Related Adverse Events

  Presenter: Edoardo G. Giannini

About Thrombocytopenia in Chronic Liver Disease

Thrombocytopenia is defined as a platelet count of less than 150,000/μL. CLD-associated thrombocytopenia may be caused by multiple factors including splenic sequestration and decreased production of TPO. It is the most common hematologic complication of CLD[3,4,5], with studies suggesting that it occurs in up to 78% of patients with cirrhosis.[6] Severe thrombocytopenia (platelet count of less than 50,000/μL) is less common, occurring in up to 11% of patients.[7] Patients with CLD and thrombocytopenia are at increased risk for bleeding, requiring recurrent platelet transfusions, increased ambulatory visits and inpatient hospital stays compared with patients with CLD without thrombocytopenia.[7,8] There is evidence that the annual health care cost of a CLD patient with thrombocytopenia is more than three times that of a

CLD patient without thrombocytopenia.[8] In addition to the potential of thrombocytopenia, especially severe thrombocytopenia(platelet count less than 50,000/μL), which increase surgical or traumatic bleeding, it may also significantly complicate routine diagnostic procedures and patient care, such as liver biopsy and medically indicated or scheduled procedures for cirrhotic patients, resulting in delayed or cancelled curative treatment.[9]

About lusutrombopag
Lusutrombopag is a once-daily, orally administered, small molecule TPO receptor agonist that triggers the production of endogenous platelets by interacting with the transmembrane domain of human TPO receptors expressed on megakaryocytes to induce the proliferation and differentiation of megakaryocytic progenitor cells from hematopoietic stem cells and megakaryocyte maturation.

On February 18, 2019, lusutrombopag received marketing authorisation by the EC for the treatment of severe thrombocytopenia in adult patients with CLD undergoing invasive procedures. Prior to this, lusutrombopag was approved by the Ministry of Health, Labour and Welfare in Japan in September 2015 for the improvement of thrombocytopenia associated with CLD in patients undergoing an elective invasive procedure, and by the U.S. Food and Drug Administration (FDA) on July 31, 2018 for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. It is currently being commercialised in Japan and the US, where it is marketed under the brand name Mulpleta®.

About Shionogi
Shionogi & Co., Ltd. ("Shionogi") is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders, cardiovascular diseases and gastroenterology. Shionogi's research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders. For more information on Shionogi, please visit www.shionogi.co.jp/en/.

Forward Looking Statement
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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