



Eddingpharm Announces Approval of Mulpleta® (Lusutrombopag) in China

OSAKA, Japan, June 30, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Eddingpharm (Head Office: Shanghai, People's Republic of China; Chief Executive Officer: Ni Xin; hereafter "Edding") has received approval for Mulpleta® (Lusutrombopag), a once-daily, orally administered, small molecule thrombopoietin (TPO) receptor agonist for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure from the Center for Drug Evaluation, NMPA¹.

Mulpleta® is a small molecule agonist of the human thrombopoietin receptor that triggers the production of endogenous platelets created by Shionogi. It has been approved and launched in Japan, the United States, and Europe. In China, about 13.^{2,3,4} million adult patients have chronic liver disease and many of them are said to be planning to receive elective invasive therapy. On the other hand, Patients faces a chronic shortage of blood for transfusions due to a growing demand for blood during advanced higher-level medical care, in addition to a lower rate of voluntary blood donation as compared to Europe, the U.S., and Japan. For these reasons, new treatment options have been sought in China.

Shionogi has concluded a license agreement⁵ with Edding to out-license the exclusive marketing rights of Mulpleta® in Mainland China, Hong Kong and Macau. Based on this license agreement, Shionogi plan to supply the product to Edding and receive an upfront payment as well as milestone payments according to post-launch sales periods.

Shionogi will continue to provide new value to society by enhancing its strengths as a drug discovery-based pharmaceutical company that it has cultivated over the years, strengthening initiatives, including cooperation with external partners, and work to solve the problems faced by patients and society.

About Eddingpharm

Established in 2001, Eddingpharm's vision and mission has always been to become China's leading supplier of patented drugs and branded drugs, bridge the gap between Chinese patients and global high quality medicines. Eddingpharm has nearly 1,000 professional representatives in 30 provinces across the country, with coverage of 19,000+ hospitals and 20,000+ pharmacies. Eddingpharm has collaborated with various multinational pharmaceutical companies, specialty pharmaceutical companies and leading R&D institutions to enrich its product portfolio by acquisitions, in-licensing, joint ventures, exclusive distribution and strategic alliances. Over the past few years, Eddingpharm rapidly expanded its business and strategically deployed resources in various fields, and is now upgrading to a whole-industry-chain entity from sole in-licensing R&D and commercialization. For more information on Eddingpharm, please visit <http://www.eddingpharm.com/EN/>

About Lusutrombopag

Lusutrombopag, which has already been approved for routine use in the US, EU, and Japan, is an orally active, small molecule agonist of the human thrombopoietin receptor that triggers the production of endogenous platelets.

About Thrombocytopenia in Chronic Liver Disease

Thrombocytopenia is a common complication of chronic liver disease (CLD) and may be caused by multiple mechanisms including splenic sequestration and decreased production of thrombopoietin⁴. 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 thrombocytopenia⁶. In addition to the potential of thrombocytopenia, especially severe thrombocytopenia, to aggravate procedural or traumatic bleeding, it may also significantly complicate routine diagnostic procedures and patient care, such as liver biopsy and medically indicated or elective procedures for cirrhotic patients, resulting in delayed or cancelled curative treatment⁷.

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, lack of availability 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.

For Further Information, Contact:

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>

References

1. [Press release by EDDING on June 29, 2023](#)
EDDING RECEIVES REGULATORY APPROVAL FOR MULPLETA® (Lusutrombopag Tablets) in MAINLAND CHINA
2. Poord F, et al. J Med Econ. 2012; 15:112-124.
3. Estimated from DM Report, Global Data
4. Estimated from Chronic Diseases Statistical Data in China 2008
5. Datamonitor report
6. [Press release on June 24, 2019](#) (PDF)
Shionogi Concludes Licensing Agreements with Eddingpharm and EOC Pharma for Lusutrombopag, a Thrombopoietin Receptor Agonist and Epertinib, an HER2/EGFR Inhibitor
7. Poord F, et al. J Med Econ. 2012; 15:112-124.
8. Hayashi H, et al. World J Gastroenterol. 2014; 20: 2595-2605.