

## **EMA Accepts MAA Submission of Shionogi's Naldemedine for the Treatment of Opioid-Induced Constipation**

**London, 24<sup>th</sup> March 2017** – Shionogi Limited, the London-based European subsidiary of Shionogi & Co., Ltd announced today that on 23<sup>rd</sup> March 2017, the European Medicines Agency (EMA) accepted its Marketing Authorisation Application (MAA) submission for naldemedine, to be marketed under the trade name Rizmoic<sup>®</sup>. Naldemedine is a once-daily, oral, 200-microgram tablet, for the treatment of opioid-induced constipation (OIC) in adult patients.

Naldemedine is a peripherally-acting mu-opioid receptor antagonist (PAMORA) that has been developed by Shionogi as a once-daily treatment for OIC. The efficacy and safety of naldemedine have been evaluated in randomised, double-blind, placebo-controlled studies in adult patients with OIC who have chronic non-cancer pain or who have cancer. OIC is a change in bowel movements caused by opioid therapy that is characterised by any of the following: reduced bowel movement frequency, development or worsening of straining to pass bowel movements, a sense of incomplete rectal evacuation, or harder stool consistency.<sup>1</sup>

“We are very pleased to announce the MAA submission for naldemedine to the EMA following submission to the US Food and Drug Administration (FDA) on 23<sup>rd</sup> March 2016 and submission to the Japanese Ministry of Health, Labour and Welfare (MHLW) on 30<sup>th</sup> March 2016. The acceptance of the MAA submission for naldemedine not only represents an important step forward in expanding the treatment options for people in Europe with this condition, but it is also another important milestone for Shionogi Limited as we continue to build the business in Europe” said Takashi Takenoshita, CEO of Shionogi Limited.

<sup>1</sup> Camilleri. M, Drossman D.A., Becker G., Webster L.R., Davies A.N., Mawe G.M. Emerging treatments in neurogastroenterology: a multidisciplinary working group consensus statement on opioid-induced constipation. *Neurogastroenterology Motil.* 2014. 26, 1386-1395

### **About Shionogi**

Shionogi Limited is the London-based, European subsidiary of Shionogi & Co., Ltd, headquartered in Osaka, Japan. Shionogi & Co., Ltd. is a Japanese Pharmaceutical company with a 139 year history discovering and developing innovative solutions. Shionogi's Research and Development currently focuses on three therapeutic areas: Infectious Diseases, Pain, and cardiovascular diseases. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit [www.shionogi.co.jp](http://www.shionogi.co.jp) For more information on Shionogi Limited, please visit [www.shionogi.eu](http://www.shionogi.eu)

### **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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