



## SHIONOGI AND PURDUE PHARMA ESTABLISH ALLIANCE FOR JOINT U.S. COMMERCIALIZATION OF NALDEMEDINE

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OSAKA, Japan and STAMFORD, Conn., Dec. 19, 2016 - [Shionogi & Co., Ltd.](#), a drug-discovery based pharmaceutical company dedicated to developing medicines that protect the health and well-being of patients, and its wholly-owned U.S. subsidiary, Shionogi Inc. (hereafter “Shionogi”), and [Purdue Pharma L.P.](#) (hereafter, “Purdue”), a privately-held pharmaceutical company founded by physicians over 60 years ago, distinguished by its pioneering research, products and medical programs directed toward alleviating pain, today announced the establishment of an alliance for the joint U.S. launch and commercialization of Symproic<sup>®</sup> (naldemedine). Symproic<sup>®</sup>, a novel peripherally-acting mu opioid receptor antagonist (PAMORA), is currently under review at FDA for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The target action date for Symproic<sup>®</sup> under the Prescription Drug User Fee Act (PDUFA) is Mar. 23, 2017.

In this alliance, Purdue’s leading expertise in the care of pain patients will be combined with Shionogi’s knowledge as the inventor and global developer of naldemedine. Purdue and Shionogi will jointly launch and commercialize Symproic<sup>®</sup>, including a comprehensive collaboration on all aspects of strategy, sales, and other activities.

“Shionogi is very pleased to create this alliance with Purdue, which is well established as the U.S. leader in providing treatments for those burdened with chronic pain. We firmly believe that Purdue is optimally positioned to bring naldemedine to market, following approval by FDA for the treatment of OIC in adult patients with chronic non-cancer pain, to benefit the appropriate patients and to the healthcare providers that care for them,” said Dr. Isao Teshirogi, President and Chief Executive Officer, Shionogi & Co., Ltd.

“This alliance brings us into an exciting new therapeutic area and offers us the opportunity to further help patients with chronic pain while advancing our plans to diversify in high need areas adjacent to pain,” said Mark Timney, President and Chief Executive Officer, Purdue Pharma L.P. “We’ve had a successful, long-term, strategic relationship with Shionogi for two decades and we look forward to continuing our work with them.”

Chadbourne & Parke LLP served as lead outside counsel for Purdue Pharma. Norton Rose Fulbright served as lead outside counsel for Shionogi.



### **About Opioid-Induced Constipation**

Constipation is one of the most commonly reported side effects associated with opioid treatment, including among patients with chronic non-cancer pain. OIC is characterized by any of the following after initiating opioid therapy: 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>

### **About Purdue Pharma L.P.**

Purdue Pharma is a privately-held pharmaceutical company and is part of a global network of independent associated companies that is known for pioneering research in chronic pain and opioids with abuse deterrent properties. The company's leadership and employees are committed to providing healthcare professionals, patients and caregivers quality products and educational resources to support their proper use. Purdue Pharma is engaged in the development, production and distribution of both prescription and over-the-counter medicines and hospital products. With Purdue Pharma's expertise in drug development, commercialization and life-cycle management, the company is diversifying in high-need areas to expand through strategic acquisitions and creative partnerships. For more information, please visit [www.purduepharma.com](http://www.purduepharma.com).

### **About Shionogi & Co., Ltd.**

Shionogi & Co., Ltd. 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," Shionogi's research and development currently targets two therapeutic areas: infectious diseases, and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic diseases and oncology/immunology. Contributing to the health and QOL 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/en/](http://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.*

## **REFERENCES**

<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.

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