

Opioid-Induced Constipation therapeutic agent 'Symproic[®] (naldemedine) Tablets 0.2mg' launched in Japan

Osaka, Japan (June 7, 2017) - Shionogi & Co., Ltd. (hereafter "Shionogi") announced that in Japan Shionogi launched 'Symproic[®] (naldemedine) Tablets 0.2mg' (generic name: naldemedine tosilate, code name: S-297995) for opioid-induced constipation.

Opioid analgesics play a central role in the treatment of cancer pain, but the side effects are an obstacle to the achievement of treatment goal and the continuation of that. It is said that constipation is recognized in 40 to 80% of patients who are treated with opioid analgesics^{1,2)} and that constipation has such a physical damage to the patients that it leads to intermit pain management by side effects induced by opioid analgesics^{3,4)}.

Symproic[®] is the first medicine created and globally developed by Shionogi. It is the only peripherally-acting mu-opioid receptor antagonist which acquired the indication for opioid-induced constipation (hereafter "OIC") in Japan, and it is expected that it offers completely different approach to treat the symptom improvement of OIC compared with the existing OIC treatment. Symproic[®] is expected to reduce constipation side effects caused by opioid analgesics, leading to realizing better pain management and contributing to improvement of quality of life (QOL) of patients who are troubled with OIC.

'Symproic[®]' Product Description

Product Name	Symproic [®] Tablets 0.2mg
Generic Name	naldemedine tosilate
Indications	Opioid-Induced Constipation
Pharmacological Effects	peripherally-acting mu-opioid receptor antagonist
Date of manufacturing and marketing approval	March 30, 2017
Date if listing in the NHI reimbursement price	May 24, 2017
Date of launch	June 7, 2017
NHI price	272.10 yen per Symproic [®] Tablet 0.2mg
Manufacturer selling company	Shionogi & Co., Ltd

1). Droney J, et al.: Support Care Cancer 16 (5) : 453-459, 2008

2). Kalso E, et al.: Pain 112 (3) : 372-380, 2004

3). Abramowitz L, et al.: J Med Econ 16 (12) : 1423-1433, 2013

4). Bell TJ, et al.: Pain Med 10 (1) : 35-42, 2009

About Shionogi

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 well-being of the patients we serve”. Shionogi’s research and development currently targets two therapeutic areas: infectious diseases and pain/CNS disorders. A 139 year old company, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives for over 50 years. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic disease and oncology/immunology. Contributing to the health and quality of life of patients around the world through development in these therapeutic areas is Shionogi’s primary goal. For more details, please visit <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.

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