

## **Shionogi Receives Approval of Injectable Analgesics for Cancer Pain, “OxiFast<sup>®</sup> Injection 10mg” and “OxiFast<sup>®</sup> Injection 50mg”**

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**Osaka, Japan, January 18, 2012** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that it has received manufacturing and marketing approval of “OxiFast<sup>®</sup> Injection 10mg” and “OxiFast<sup>®</sup> Injection 50mg” (generic name: oxycodone hydrochloride hydrate) for the treatment of cancer pain in Japan on January 18, 2012.

Shionogi has been providing two oral oxycodone products, OxyContin<sup>®</sup> tablets (oxycodone hydrochloride extended release tablet) since 2003 and OxiNorm<sup>®</sup> powder (oxycodone hydrochloride powder) since 2007, for the relief of moderate to severe pain in patients suffering from many types of cancer. However, patients with difficulty taking oral drugs have had to change their therapy to other opioid analgesics. Therefore, the Japanese Society for Palliative Medicine petitioned the Ministry of Health, Labor and Welfare (hereafter “MHLW”) in 2007 for the development of an injectable oxycodone product. The Investigational Committee for Usage of Unapproved Drugs, established by the MHLW agreed with the need for the development of injectable oxycodone product, and Shionogi decided to develop OxiFast<sup>®</sup> injection. After the launch of OxiFast<sup>®</sup> injection, patients with moderate to severe cancer pain who have difficulty taking oral drugs will have access to treatment with an injectable oxycodone formulation which includes the same ingredient as OxyContin<sup>®</sup> tablets and OxiNorm<sup>®</sup> powder.

Shionogi continues to provide its full support to our Oxycodone family of products, including “OxyContin<sup>®</sup> tablets,” “OxiNorm<sup>®</sup> powder” and now “OxiFast<sup>®</sup> injection”, so that more patients suffering from cancer pain can have a better quality of life.

### **OxiFast<sup>®</sup> Injection Product Overview**

Product Name:	OxiFast <sup>®</sup> Injection 10mg, OxiFast <sup>®</sup> Injection 50mg
Generic Name:	Oxycodone hydrochloride hydrate
Indications:	Moderate to severe pain associated with all types of cancer
Dosage and Administration:	Generally to adults, continuous intravenous administration or continuous subcutaneous administration of 7.5-250mg/day oxycodone hydrochloride (anhydride). Arbitrarily, dosage to be increased or decreased depending on age or symptoms
Acquisition of Manufacturing and Marketing Approval:	January 18, 2012

**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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