

## **Shionogi Provides Pirespa<sup>®</sup> 200mg Tablet to ILDONG PHARMACEUTICAL for the Treatment of Idiopathic Pulmonary Fibrosis in South Korea**

---

**Osaka, Japan, October 12, 2012** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi” or “the Company”) today announced that it began to supply Pirespa<sup>®</sup> 200mg tablet (generic name: pirfenidone) to ILDONG PHARMACEUTICAL Co., Ltd. (Head Office: Seoul; Chairman & CEO: Jung-chi Lee; hereafter “ILDONG”) for the treatment of idiopathic pulmonary fibrosis (IPF) in South Korea from the end of September, 2012. Pirespa<sup>®</sup> is commercially available in South Korea through ILDONG since October 8, 2012.

Shionogi developed pirfenidone for the treatment of IPF in Japan after entered into the in-licensing agreement with the U.S.-based Marnac, Inc. and KDL, Inc., Tokyo in 1997. The Company received a marketing and manufacturing approval of pirfenidone for IPF in Japan in October and launched it as Pirespa<sup>®</sup> in December, 2008. It was the first time for the product to become available all over the world. Pirfenidone has a new mechanism of action which can directly inhibit fibrosis and the product is expected to reduce the progression of IPF. The product has already been used for a lot of patients with IPF as a new treatment option.

For the patients with IPF in South Korea, Shionogi and ILDONG entered into the licensing agreement for the sale of pirfenidone in May, 2011, and ILDONG had developed the product and received the approval after a fast track procedure as an orphan drug at the end of July, 2012. For the launch of Pirespa<sup>®</sup> by ILDONG in October, Shionogi began to provide the product to ILDONG at the end of September, 2012.

Shionogi will continue to support the treatment of patients with IPF by the stable supply of Pirespa<sup>®</sup> as well as by the provision of its accumulated clinical data in Japan, and to cooperate closely with ILDONG for the establishment of further clinical evidence of the product in Asia.

### **For Reference:**

#### **About ILDONG PHARMACEUTICAL Co., Ltd.**

Establishment:	March 14, 1941
Representative:	Chairman & CEO, Jung-chi Lee
Head Office:	60, Yangjae-dong, Seocho-gu, Seoul
Description of Business:	ILDONG is a South Korean pharmaceutical company with the philosophy of “Excellence and Contribution to the Health and Happiness of Mankind”, and which has worked to develop, produce and distribute superior pharmaceutical products for 70 years. In particular, ILDONG is viewed as a

leading company in the production of vitamins, lactobacillus, antibiotics, and gastrointestinal preparations.

### **About Idiopathic Pulmonary Fibrosis**

Idiopathic pulmonary fibrosis is a medical condition of unknown etiology with poor prognosis in which progressive fibrosis of the alveolar walls produces irreversible “honeycomb lung<sup>\*</sup>”. In general, restrictive impairment (reduction of vital capacity (VC) and total lung capacity (TLC)) is evident. As the symptom (fibrosis of the alveolar walls) progresses, gas exchange in the lungs (exchange of oxygen and carbon dioxide) becomes difficult. In some cases, oxygen therapy becomes necessary. Because of its severity, IPF is designated as a “specified disease” (in other words, an intractable disorder).

\* Honeycomb lung: A high-resolution CT scan of the lung yields a honeycomb pattern.

### **Product Overview**

Product Name:	Pirespa <sup>®</sup> 200mg tablet
Generic Name:	Pirfenidone
Effect:	Idiopathic pulmonary fibrosis
Form and Content:	Film-coated tablet containing 200mg of pirfenidone in one tablet
Dosage and Administration:	Generally in adults, one 200mg tablet as a primary dosage is administered orally three times daily (600mg in a day) after meal. The dosage is increased by 200mg increments per admin up to 600mg per admin (1800mg in a day), examining condition of the patient. The dosage should be adjusted according to the patient’s condition.

### **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.*

**For further information, contact:**

Corporate Communications Department

Shionogi & Co., Ltd.

Telephone: +81-6-6209-7885

Fax: +81-6-6229-9596