

**ILDONG PHARMACEUTICAL Receives a Marketing and Manufacturing  
Approval for Pirespa<sup>®</sup> 200mg Tablet  
Idiopathic Pulmonary Fibrosis Treatment**

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**Osaka, Japan, August 8, 2012** - Shionogi & Co., Ltd. (Head Office: Osaka; President: Isao Teshirogi, Ph.D.; hereafter “Shionogi” or “the Company”) today announced that ILDONG PHARMACEUTICAL Co., Ltd. (Head Office: Seoul; Chairman & CEO: Jung-chi Lee; hereafter “ILDONG”) received a marketing and manufacturing approval for idiopathic pulmonary fibrosis (IPF) treatment of Pirespa<sup>®</sup> 200mg tablet (generic name: pirfenidone) on July 31, 2012. ILDONG will launch Pirespa<sup>®</sup> in South Korea as soon as possible after receiving the approval.

Shionogi in-licensed pirfenidone from the U.S.-based Marnac, Inc. and KDL, Inc., Tokyo, and received a marketing and manufacturing approval for IPF in October and launched it as Pirespa<sup>®</sup> in December, 2008 in Japan for the first time in the world. Pirfenidone is a promising therapeutic agent which is expected to inhibit the progression of IPF through a new mechanism of action inhibiting fibrosis directly and offering a new option for IPF treatment.

Shionogi entered into licensing agreement for the sale of pirfenidone in South Korea with ILDONG on May, 2011. Following the execution of agreement, ILDONG has developed it and submitted a New Drug Application of pirfenidone for the treatment of IPF to Ministry of Health and Welfare in April, 2012 and received the approval after a fast track procedure as an orphan drug.

Shionogi will provide the product to ILDONG and receive the royalty payment based on the net sales of the drug by ILDONG under the agreement in May, 2011. The royalty will not impact Shionogi’s consolidated earnings forecast for fiscal 2012.

Shionogi is delightful to provide Pirespa<sup>®</sup> to patients suffering from IPF not just in Japan but in South Korea through ILDONG which has long-time friendly relations with the Company. Shionogi anticipates that accumulated clinical data of pirfenidone in Japan will contribute to the treatment of oversea patients suffering from IPF.

**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. A news release from ILDONG and additional information is available at <http://www.ildong.com>

### **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).

<sup>\*</sup> 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.*

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