

December 22, 2006  
Shionogi & Co., Ltd.

## **Results of Phase III Clinical Trials of the Idiopathic Pulmonary Fibrosis Treatment S-7701**

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**Osaka, December 22, 2006** — Shionogi & Co., Ltd. (Head Office: Osaka; President: Motozo Shiono) today announced that it has achieved the primary objectives of Phase III clinical trials for the idiopathic pulmonary fibrosis treatment S-7701 (generic name: pirfenidone), which the Company is developing in Japan under a license from U.S.-based Marnac, Inc. and KDL, Inc., Tokyo.

Idiopathic pulmonary fibrosis (IPF) is a medical condition of unknown etiology with poor prognosis in which progressive fibrosis of the alveolar walls produces irreversible “honeycomb lung”\*. 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).

Under development as a treatment for IPF, S-7701 has been designated as an orphan drug (a drug used to treat a rare disease) by the Pharmaceuticals and Medical Devices Agency.

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

In the Phase III clinical trials for this drug with VC change (from before commencement of treatment to 52 weeks after commencing treatment) as the primary endpoint, both high and low doses of the drug (600mg/l per day, three times a day and 400mg/l per day, three times a day, respectively), significantly inhibited worsening of the condition compared with a placebo.

While continuing to conduct further analysis and study, Shionogi plans to expedite the application process based on these clinical results, with the intention of submitting a new drug application (NDA) within the current fiscal year.

In the process of developing this drug, Shionogi has received many earnest inquiries from patients with IPF and their families regarding the extent of progress of development, and urgent requests for the medication.

With this situation in mind, Shionogi intends to do its best to expedite submission and approval for S-7701 in order to offer the quickest possible relief to patients suffering from this disease.

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