SHIONOGI & CO., LTD.

Shionogi Files an Application for an Anti-hypertension Drug "S-474474", a Combination of Irbesartan and Trichlormethiazide

Osaka, Japan, July 30, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it submitted an application for a manufacturing and marketing approval for S-474474 (product code), a combination of an angiotensin II receptor blocker (ARB), Irbetan® (generic name: irbesartan[*1]) and a thiazidal anti-hypertensive diuretic, Fluitran® (generic name: trichlormethiazide[*2]), to the Ministry of Health, Labour and Welfare in Japan.

S-474474 is a combination of Irbetan® (100mg or 200mg), ARB and Fluitran® 1mg, antihypertensive diuretics. If approved, it will be the first combination drug of ARB and Fluitran® 1mg which is prescribed best among the thiazidal anti-hypertensive diuretics in Japan. In the Japanese guideline for hypertensive treatments, the combination of a kind of renin-angiotensin system suppressive drugs and a low dose of antihypertensive diuretics is recommended from the viewpoints of synergistic action of antihypertensive effects and less side effects related to electrolyte and glucose metabolism of diuretics.

In a clinical trial in Japan, once-daily oral admisitration of S-474474 showed more effective for both systolic and diastolic blood pressures than Irbetan® alone and small change in uric acid level as a side effect of diuretics before and after the administration. It is expected S-474474 contributes to the therapy for patients with hypertension in Japan from the viewpoints of both effectiveness and safety.

Shionogi positions Irbetan® as one of its strategic products in domestic sales in the Third Medium-Term Business Plan and has strived to deliver the product, which is evaluated globally, to more patients in Japan. In last June, Shionogi has entered into a license agreement for the co-marketing of "DSP-8153" (product code), a combination of irbesartan and amlodipine besilate with Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka; President & CEO: Masayo Tada)
Shionogi will make efforts to improve convenience of patients with hypertension by launch of these combination drugs and also do its best to further contribute to therapy for hypertension in Japan by maximizing the value of "irbesartan family".

Reference:
***1:** Irbesartan is a long-acting ARB originally created by Sanofi (Headquarters: France) with a long half-life in blood and a 24-hour-lasting blood pressure-lowering effect, having high anti-hypertensive effect in mild to severe hypertension. Based on the large-scale clinical trials, IDNT and IRMA2, which are often cited in the major international guidelines, this drug is also recognized as the only one ARB with evidence for its renoprotective effect covering both early-stage and overt nephropathy. Moreover, irbesartan shows also a partial agonistic effect on PPARγ (Peroxisome Proliferator-activated receptor-γ), which involves in the regulation of

lipid and glucose metabolisms, and anti-inflammatory effects, and is expected to have additional therapeutic effets in patients with metabolic disorders.

***2:** Trichlormethiazide is a thiazidal antihypertensive diuretic originally created by the US based Schering-Plough Corp. (now Merck & Co., Inc.) and has been marketed for more than 50 years in Japan. It reduces the burden of heart by putting internal extra water outside a body and increasing the amount of urine and suppressing reuptake of sodium and water in the distal tubule, which is the best seller of diuretics in Japan used in the treatment of essential hypertension, edema and premenstrual symdrome.

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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