

Shionogi & Co., Ltd.

Angiotensin II Receptor Blockers (ARBs) for treatment of Hypertension

**Irbetan<sup>®</sup> 50mg and 100mg Tablets Launches**

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June 23, 2008 -- Shionogi & Co., Ltd. (Head Office: Osaka; President: Isao Teshirogi) today announced that it is scheduled to launch 50mg and 100mg formulations of Irbetan<sup>®</sup> (generic name: Irbesartan), a hypertension treatment in Japan on July 1.

Discovered by French pharmaceutical company Sanofi-Aventis and co-developed in overseas countries by Sanofi-Aventis and Bristol Myers Squibb, a U.S. pharmaceutical company, Irbesartan is a long-acting angiotensin II receptor blocker (ARB). In addition to having a stable hypotensive effect lasting 24 hours on mild to severe hypertension, Irbesartan has received a high evaluation outside Japan since its launch in 1997 as an ARB whose large-scale clinical trials including IDNT and IRMA 2 are often cited in the major guidelines abroad.

The drug is on the market in 86 countries. Worldwide sales in 2007 totaled about 300.0 billion Japanese yen, making it one of the leading ARB brand.

Shionogi has long been conducting educational activities for the diagnosis and treatment of hypertension in elderly patients, based on the results of the large-scale clinical trials 'JATOS' with antihypertensive Landel<sup>®</sup>, a calcium antagonist. While conducting these activities, Shionogi has asked Atsuya Furuta who was a former manager of the Yakult Swallows pro baseball team, and has experience as a catcher, a key defensive position and as a president

of the Japan Professional Baseball Players Association, to be the symbol in a new initiative to enhance information on CKD(chronic kidney disease) provided to healthcare professionals. This initiative is aimed at raising awareness of the importance of “defending” the kidneys and safely treating hypertension under the phrase “Beat the CKD”

With its hyperlipidemia treatment Crestor<sup>®</sup>, Shionogi has focused on contributing to the treatment of many hyperlipidemia patients. In addition, Shionogi will do its utmost to make a larger contribution to treatment in the circulatory and lipid metabolism fields by getting Irbetan<sup>®</sup> prescribed to as many hypertension patients as possible.

### **Irbetan<sup>®</sup> Product Overview**

Product Name:	Irbetan <sup>®</sup> 50mg tablets, Irbetan <sup>®</sup> 100mg tablets
Generic Name:	Irbesartan
Effect:	Antihypertensive
Form and Content:	White to yellowish-white, round, scored, film-coated tablets containing 50mg or 100mg of Irbesartan in one tablet
Dosage and Administration:	Generally in adults, one 50mg or 100mg tablet is taken orally each day. The dosage may be increased or reduced as appropriate depending on age and symptoms, but should not exceed 200mg per day.
Approval Date:	April 16, 2008
NHI Drug Price Listing:	June 13, 2008
Price:	50mg tablets: 80.10(Yen) 100mg tablets: 154.20(yen)
Launch Date:	July 1, 2008

**For Reference:**

**About Angiotensin II Receptor Blockers (ARBs)**

ARBs reduce blood pressure by preventing angiotensin II, a physiologically active substance that constricts blood vessels and increases blood pressure, from binding to sites of action (receptors).

**About IRMA 2**

IRMA 2 (Irbesartan in Patients with Type 2 Diabetes and Microalbuminuria study) was conducted on 590 hypertensive patients with Type 2 diabetes and microalbuminuria. The study verified that Irbesartan inhibited progression from early nephropathy to overt nephropathy at 300mg/day. Compared with the placebo group, irbesartan significantly reduced the amount of albumin in the urine, and restrained progression to overt proteinuria.

**About IDNT**

The IDNT (Irbesartan Diabetic Nephropathy Trial) compared Irbesartan at 300mg/day with amlodipine (a calcium antagonist) and a placebo in 1,715 hypertensive patients with Type 2 diabetes and nephropathy to evaluate inhibition of kidney events. Irbesartan was the first ARB to demonstrate better control of events in the overt nephropathy stage compared with a calcium antagonist.

**For further information:**

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