

## **Shionogi Launches “IRTRA<sup>®</sup> Combination Tablets LD/HD” for the Treatment of Hypertension**

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**Osaka, Japan, September 4, 2013** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that it has launched “IRTRA<sup>®</sup> Combination Tablets LD/HD”, a combination product of long-acting ARB (angiotensin II receptor antagonist) irbesartan (brand name: IRBETAN<sup>®</sup>) and an diuretic trichlormethiazide (brand name: FLUITRAN<sup>®</sup>) on September 4, 2013 in Japan. This drug was listed in the NHI (National Health Insurance) drug price standard as of August 27, 2013.

“IRTRA<sup>®</sup> Combination Tablets LD ” is a combination of irbesartan 100mg/trichlormethiazide 1mg and “IRTRA<sup>®</sup> Combination Tablets HD ” is a combination of irbesartan 200mg/trichlormethiazide 1mg. Once-daily oral administration of IRTRA<sup>®</sup> Combination Tablets LD/HD showed more effective for both systolic and diastolic blood pressures than IRBETAN<sup>®</sup> alone in patients with uncontrolled hypertension.

In the Japanese guidelines for hypertensive treatments, a combination of renin-angiotensin system suppressive drugs and a low dose of antihypertensive diuretics is recommended for the therapy from the viewpoints of synergistic antihypertensive effects as well as less side effects related to the electrolyte and glucose metabolism of diuretics. This product is the first combination including FLUITRAN<sup>®</sup> which has been widely used in Japan as a diuretic since 1960.

Shionogi will commit its efforts to make IRTRA<sup>®</sup> Combination Tablets LD/HD as widely available as possible to patients with hypertension, and also to further contribute to a better therapy for hypertension by promoting activities to provide the information of this new treatment option to medical institutions.

## IRTRA® Product Overview

Product Name:	IRTRA® Combination Tablets LD/HD
Generic Name:	Irbesartan / Trichlormethiazide
Indication:	Hypertension
Form and Content:	IRTRA® Combination Tablets LD : Pale red film-coated tablets containing 100mg of irbesartan and 1mg of trichlormethiazide in one tablet IRTRA® Combination Tablets HD : Pale red film-coated tablets containing 200mg of irbesartan and 1mg of trichlormethiazide in one tablet
Dosage and Administration:	Generally in adults, one LD or HD tablet is taken orally each day. IRTRA® Combination Tablets should not be used as a first-line treatment for hypertension.
Approval Date:	June 28, 2013
Manufacturer and Distributor:	Shionogi & Co.,Ltd.
Date of Approval:	June 28,2013
Date of NHI price listing:	August 27,2013
NHI drug price standard:	IRTRA® Combination Tablets LD one tablet: 130.50 yen IRTRA® Combination Tablets HD one tablet: 195.80 yen
Package:	IRTRA® Combination Tablets LD : (PTP) 100 tablets (10 tablets x 10) 500 tablets (10 tablets x 50) 700 tablets (14 tablets x 50) (Bottle) 500 tablets IRTRA® Combination Tablets HD : (PTP) 100 tablets (10 tablets x 10) 500 tablets (10 tablets x 50) 700 tablets (14 tablets x 50) (Bottle) 500 tablets

**About irbesartan**

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.

**About trichlormethiazide**

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 one of wide used diuretics in Japan used in the treatment of essential hypertension, edema and premenstrual syndrome.

**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.

Osaka Telephone: +81-6-6209-7885

Fax: +81-6-6229-9596

Tokyo Telephone: +81-3-3406-8164

Fax: +81-3-3406-8099