

September 28, 2012

Dainippon Sumitomo Pharma Co., Ltd.

**Dainippon Sumitomo Pharma obtains manufacturing and marketing approval  
for “AIMIX<sup>®</sup> Combination Tablets LD/HD”**

Osaka, Japan, September 28 2012 – Dainippon Sumitomo Pharma Co., Ltd. (DSP, Headquarters: Osaka, Japan; President & CEO: Masayo Tada) announces that as of September 28, 2012, DSP has obtained manufacturing and marketing approval in Japan for anti-hypertension drug “AIMIX<sup>®</sup> Combination Tablets LD/HD” from the Ministry of Health, Labour and Welfare.

AIMIX<sup>®</sup> Combination Tablets LD/HD have a 24-hour-lasting antihypertensive effect and are a combination product of irbesartan (brand name: AVAPRO<sup>®</sup>), a long-acting ARB (angiotensin II receptor antagonist) and amlodipine besilate (brand name: AMLODIN<sup>®</sup>), a calcium antagonist with a strong, sustained hypotensive effect. DSP developed these products and submitted an application for manufacturing and marketing approval in November 2011. Clinical trials in Japan demonstrated the efficacy of AIMIX<sup>®</sup> Combination Tablets LD/HD in patients with hypertension uncontrolled by usual doses of irbesartan or amlodipine besilate alone.

“AIMIX<sup>®</sup> Combination Tablets LD” is a combination of irbesartan 100mg/ amlodipine 5mg and “AIMIX<sup>®</sup> Combination Tablets HD” is a combination of irbesartan 100mg/ amlodipine 10mg. AIMIX<sup>®</sup> Combination Tablets HD is the first combination product in Japan including 10mg of amlodipine.

In June, 2012, DSP and Shionogi & Co., Ltd. (Shionogi, Headquarters: Osaka; President & CEO: Isao Teshirogi, Ph.D.) entered into a license agreement for the co-marketing in Japan of AIMIX<sup>®</sup> Combination Tablets LD/HD. Both companies plan to launch AIMIX<sup>®</sup> Combination Tablets LD/HD after they are listed on the national health insurance drug price standard.

By promoting activities to provide information to medical institutions in parallel with Shionogi, DSP aims to provide AIMIX<sup>®</sup> Combination Tablets LD/HD to as many patients as possible with hypertension in Japan, further contributing to therapy for hypertension.

[Attached reference: Profiles of AIMIX<sup>®</sup> Combination Tablets LD/HD, irbesartan and amlodipine besilate]

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<Reference>

## Profile of “AIMIX<sup>®</sup> Combination Tablets LD/HD”

[Product Name]	AIMIX <sup>®</sup> Combination Tablets LD AIMIX <sup>®</sup> Combination Tablets HD
[Generic Name]	irbesartan/ amlodipine besilate
[Content / Description]	AIMIX <sup>®</sup> Combination Tablets LD: Pale yellow film-coated tablets containing 100mg of irbesartan and 5mg of amlodipine (6.93mg of amlodipine besilate) per tablet. AIMIX <sup>®</sup> Combination Tablets HD: Pale yellow film-coated tablets containing 100mg of irbesartan and 10mg of amlodipine (13.87mg of amlodipine besilate) per tablet.
[Indication]	Hypertension
[Dose and Administration]	The usual recommended adult dose is one tablet (100mg/5mg or 100mg/10mg of irbesartan/amlodipine) once daily. AIMIX <sup>®</sup> Combination Tablets should not be used as a first-line treatment for hypertension.
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma Co., Ltd.

### About irbesartan

Irbesartan is a long-acting ARB (angiotensin II receptor antagonist) originally created by Sanofi (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. Irbesartan was launched globally in 1997, and 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 in hypertensive type 2 diabetic patients covering both early-stage and overt nephropathy. It is also highly regarded as one of the top ARB brands. In the domestic market, Irbesartan has been commercialized since July 2008 as “AVAPRO<sup>®</sup>” (DSP’s brand name) and “Irbetan<sup>®</sup>” (Shionogi’s brand name).

The indication, dose and administration approved in Japan are as follows:

Indication: hypertension

Dose and Administration: the usual recommended dose is 50 to 100mg once daily administered orally. The dose may be adjusted according to the patient’s age or response to treatment with a maximum dose of 200mg once daily.

### About amlodipine besilate

Amlodipine besilate is a calcium antagonist with a strong, stable and sustained hypotensive effect and is highly acclaimed in Japan and overseas. It was launched in Japan by DSP in December 1993 as “AMLODIN®”.

It has made the wider treatment for early to severe patients with hypertension possible since the prescription by 10mg of amlodipine was approved in February 2009 in Japan, which is a standard dosage in global markets. Based on results from large-scale clinical trials carried out overseas such as ASCOT-BPLA and CAMELOT, evidence for cerebroprotection and cardioprotection have been reported and prescriptions are widely written with the expectation of an improved prognosis for patients with hypertension.

The indication, dose and administration approved in Japan are as follows:

Indication: hypertension, angina pectoris

- Hypertension

Adults: the usual recommended dose is 2.5 to 5mg once daily. The dose may be adjusted according to the patient's response to treatment. The dose can be increased up to 10mg once daily when blood pressure is uncontrolled.

Pediatrics: the usual dose in patients aged 6 years and over is 2.5mg once daily. The dose may be adjusted according to the patient's age, weight, and response to treatment.

The underlined section applies to “AMLODIN® Tablets 2.5mg/5mg” and “AMLODIN® OD Tablets 2.5mg/5mg”.

- Angina pectoris:

The recommended adult dose is 5mg once daily. The dose may be adjusted according to the patient's response to treatment.