

November 30, 2011
Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma announces application for manufacturing and marketing approval for “DSP-8153”, combination product of irbesartan and amlodipine besilate

Dainippon Sumitomo Pharma Co., Ltd. (DSP, Headquarters: Osaka, Japan; President: Masayo Tada) announces that it submitted an application for manufacturing and marketing approval for “DSP-8153” (product code), a combination product of anti-hypertension drug irbesartan (brand name: AVAPRO[®]) and amlodipine besilate (brand name: AMLODIN[®]) to the Ministry of Health, Labor and Welfare in Japan as of November 18, 2011.

Irbesartan is a long-acting ARB (angiotensin II receptor antagonist) 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 in hypertensive type 2 diabetic patients covering both early-stage and overt nephropathy, and is highly regarded as one of the top ARB brands.

Amlodipine besilate is a calcium antagonist with a stable, sustained hypotensive effect and is highly acclaimed in Japan and overseas. 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.

DSP-8153 is a combination product of irbesartan with evidence for renoprotective effects and amlodipine besilate with evidence for cerebroprotective and cardioprotective effects. In clinical trials in Japan, DSP-8153 was effective for patients with essential hypertension uncontrolled by irbesartan or amlodipine besilate alone. Moreover, two doses are included in the application for this combination product, irbesartan 100mg/ amlodipine 5mg and irbesartan 100mg/ amlodipine 10mg. If approved, this will be the first combination product in Japan including 10mg of amlodipine.

By expanding the therapeutic options for patients, DSP expects to further contribute to therapy for hypertension.

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