News Release

February 20, 2012

Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma Submits Application Based on Public Knowledge for long-acting calcium antagonist AMLODIN® tablets/OD tablets for the Additional Indication of "Hypertension in pediatric patients"

Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) has submitted an "Application Based on Public Knowledge[*1]" for long-acting calcium antagonist AMLODIN® tablets 2.5mg/5mg and AMLODIN® OD tablets 2.5mg/5mg (generic name: amlodipine besilate) for the additional indication of hypertension in pediatric patients (6 years of age and older) as of February 20, 2012.

Amlodipine is characterized by sustained clinical efficacy and a large body of clinical evidence. It is indicated for the treatment of hypertension and angina pectoris. Since its launch in Japan in 1993, it has been widely prescribed as one of the first-line drugs for the treatment of hypertension.

In regard to the additional indication for pediatric use of amlodipine, after receiving the results from the "Evaluation committee on unapproved or off-label drugs with high medical needs[*2]", the Ministry of Health, Labour and Welfare issued a request to DSP for development on May 21, 2010. In addition, at a meeting held January 27, 2012, the First Committee of the "New Drugs of the Pharmaceutical Affairs and Food Sanitation Council" conducted the preliminary evaluations regarding the additional indication for pediatric use of amlodipine and concluded that an application based on public knowledge would be allowed. Therefore DSP was able to submit the application.

It has been reported in Japan that symptoms of high blood pressure are observed in 0.1% to 1% of the upper grades of elementary school to junior high school students and in about 3% of high school students[*3]. By obtaining an additional indication for the pediatric use of AMLODIN® tablets/OD tablets, DSP believes it can help pediatric patients with hypertension to reach their appropriate blood pressure target values and therefore further contribute to the suppression of cardiovascular events.

DSP believes that by continuing to actively promote the approval of unapproved or off-label drugs it can meet the diverse needs of patients, and further contribute to improved medical care.

*1 An Application Based on Public Knowledge is a marketing authorization application that seeks supplemental indication approval for a currently approved drug. In this system an application is submitted based on medical and pharmacological public knowledge of a drug's safety and efficacy and does not require that additional clinical studies be conducted, in whole or in part.

*2 The “Evaluation committee on unapproved or off-label drugs with high medical needs” is a committee established to promote the development of unapproved or off-label drugs by pharmaceutical companies that are approved for use in Europe and the United States, but not approved in Japan. It is organized by the Ministry of Health, Labour and Welfare and consists of academic experts in medical and pharmaceutical fields.

*3 Japanese Society of Hypertension: Hypertension treatment guidelines published 2009. Life Sciences: 83, 2009

<Reference>

Profile of “AMLODIN®”

[Product Name]	AMLODIN® tablets 2.5mg, 5mg, 10mg AMLODIN® OD tablets 2.5mg, 5mg, 10mg

(Note) This time an application based on public knowledge was submitted for AMLODIN® tablets 2.5mg/5mg and AMLODIN® OD tablets 2.5mg/5mg.

[Generic Name]	Amlodipine Besilate
[Indication]	Hypertension, angina pectoris.
[Dose and Administration]	Hypertension: The usual adult dose for oral use is 2.5 to 5mg of amlodipine once daily. This dose may be adjusted depending on symptoms. In the case that the dose is ineffective it can be increased up to 10mg once a day. Angina pectoris: The usual adult dose is 5mg of amlodipine administered orally once a day. The dose may be adjusted depending on symptoms.

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