



For Immediate Release

May 31, 2010

Dainippon Sumitomo Pharma Co., Ltd.

Application for partial change of approval of the dosage and administration of MEROPEN[®], a carbapenem antibiotic preparation

Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka, Japan; President: Masayo Tada; hereinafter called “DSP”) announced that it has filed an application as of May 27, 2010 for partial change of approval of the dosage and administration of MEROPEN[®], a carbapenem antibiotic preparation, more specifically a change of the maximum daily dose from 2 g to 3 g for serious illness and intractable case of general infections in Japan.

MEROPEN[®] is DSP’s self-developed carbapenem antibiotic preparation for injection, which was launched in Japan in September 1995. This drug is widely used for various types of moderate to severe infectious diseases caused by gram-positive / gram-negative bacteria. This medicine is sold by DSP and AstraZeneca, DSP’s licensee, in more than 100 countries collectively in the world.

With respect to dosage and administration of an antibacterial drug for serious illness and intractable case of general infections, particular attention has been paid in recent years to the importance of “optimal” administration based on PK-PD theory (*). In this connection, it is often pointed out that dosage levels approved in Japan are questionably low compared with those in many foreign countries. The approved maximum daily dose of MEROPEN[®] in Japan is currently 2 g for serious illness and intractable case of general infections. With the presumption that the need may arise in Japan for administration of 3 g per day of MEROPEN[®] which will show apparently promising results in clinical practices as well as significant bacteriological effects, DSP has filed an application for partial change of approval of the dosage and administration of this drug.

DSP expects to further contribute to improvement in the survival rate of serious infections by providing a new option to infectious disease therapy in Japan through an acquisition of approval of the partial change which enables administration of up to 3 g per day of MEROPEN[®] for serious illness and intractable case of general infections.

(*) PK-PD theory:

This is a concept to design the optimal administration of an anti-microbial agent by evaluating its efficacy and safety in connection with pharmacokinetics (PK), which shows how an anti-microbial agent concentration changes within human body, and pharmacodynamics (PD).