News Release

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Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma files an application in Japan for a partial change in the approved dosage and administration of MEROPEN®, a carbapenem antibiotic preparation, when used for the treatment of bacterial meningitis

Osaka, Japan, January 22, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) announces that today it has filed an application in Japan for the partial change in dosage and administration of MEROPEN®, a carbapenem antibiotic preparation, more specifically a change in the daily dose to 6g (potency), when used for the treatment of bacterial meningitis.

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.

Bacterial meningitis is a severe infection that develops when bacteria invade the marrow cavity. In Japan, the infection is often caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*. Even today with the development of antimicrobial therapy the fatality rate after onset is still high and even when treated, severe after effects from the disease may remain. Therefore, it is said that rapid diagnosis including the detection of the causative bacteria and the start of early and appropriate therapy are very important.

Currently, for severe/refractory cases of general infections including bacterial meningitis, the maximum approved dose of MEROPEN® in Japan is 3g (potency) daily. However, the recommended dose overseas and according to Japanese and international guidelines is 6g daily, a discrepancy compared to the approved dose in Japan.
DSP expected promising results in clinical practices as well as significant bacteriological effects from a 6g (potency) daily dose of MEROPEN® against bacterial meningitis. Therefore, DSP conducted clinical studies and submitted an application for a partial change in the approved dosage and administration.

From the potential approval of the 6g (potency) daily administration of MEROPEN® for bacterial meningitis, DSP hopes to further contribute to the treatment of infectious diseases by providing a new option to improve the survival rate for patients with bacterial meningitis in Japan.

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