News Release

December 20, 2013

Dainippon Sumitomo Pharma Co., Ltd.

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

Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Head Office: Osaka, Japan; President: Masayo Tada) announces that as of December 20 it obtained the approval in Japan for partial change in dosage and administration of MEROPEN®, a carbapenem antibiotic preparation, more specifically a change in the typical daily dose in adults to 6g (potency) (120 mg/kg/day and maximum 6g (potency) in children), when used for the treatment of bacterial meningitis.

MEROPEN® is a carbapenem antibiotic preparation for injection developed by DSP and 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. 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 such therapy successfully prevented deaths, severe aftereffects 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.

To this date, for severe / refractory cases of general infections including bacterial meningitis, the maximum approved dose of MEROPEN® in Japan was 3g (potency) daily. However, the approved dose overseas and recommended dose according to Japanese and overseas guidelines was 6g (potency) daily, a discrepancy compared to the approved dose in Japan.

DSP expected 6g (potency) daily dose of MEROPEN®, which can achieve higher clinical and bacteriological effects, is beneficial to patients with bacterial meningitis. Therefore, DSP conducted clinical studies and in January 2013 submitted an application for a partial change in the approved dosage and administration, which was approved today.

With the approval of the 6g (potency) daily administration of MEROPEN® for bacterial meningitis now granted, 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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