News Release

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Dainippon Sumitomo Pharma Co., Ltd.

Approval obtained for partial change in 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 obtained approval for partial change in 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 severe / refractory 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 severe / refractory infections, particular attention has been paid in recent years to the importance of "optimal" administration based on PK-PD theory (*). In this connection, it has often been pointed out as a problem that approved dosage in Japan is low compared with those in many foreign countries. The approved maximum daily dose of MEROPEN® in Japan was 2 g for severe / refractory infections, while as a result of acquisition of the approval of partial change in dosage and administration, an administration of 3 g per day of MEROPEN® has become possible, which is expected to show promising results in clinical practices as well as significant bacteriological effects.

DSP expects to further contribute to improvement in the survival rate of various infections by providing information from the viewpoint of proper use of antibiotic preparations in terms of dosage and administration of MEROPEN® for 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).

<An outline of MEROPEN® is described in Reference.>

＜Reference＞

Profile of MEROPEN®

[Brand Name]	MEROPEN® for Intravenous Drip Infusion Vial 0.25 g MEROPEN® for Intravenous Drip Infusion Vial 0.5 g MEROPEN® for Intravenous Drip Infusion Kit 0.5 g
[Generic Name]	Meropenem hydrate
[Indications]	1. Infection （Indicated bacteria） Meropenem-susceptible strains of *Staphylococcus* sp., *Streptococcus* sp., *Streptococcus pneumoniae*, *Enterococcus* sp., *Neisseria meningitidis, Moraxella (Branhamella) catarrhalis*, *Escherichia coli*, *Citrobacter* sp., *Klebsiella* sp., *Enterobacter* sp., *Serratia* sp., *Proteus* sp., *Providencia* sp., *Haemophilus influenzae*, *Pseudomonas* sp.,*Pseudomonas aeruginosa, Burkholderia cepacia, Bacteroides* sp. and *Prevotella* sp. （Indications） Septicemia, deep-seated skin infection, lymphangitis / lymphadenitis, secondary infection of traumatic wound, burn wound or operative wound, perianal abscess, osteomyelitis, arthritis, tonsillitis (including peritonsillar abscess), pneumonia, lung abscess, pyothorax, secondary infection in chronic respiratory disease, complicated cystitis, pyelonephritis, peritonitis, cholecystitis, cholangitis, liver abscess, intrauterine infection, uterine adnexitis, parametritis, purulent meningitis, endophthalmitis (including panophthalmitis),otitis media, sinusitis, phlegmon around the jaw, and gnathitis 2. Febrile neotropenia
[Dosage and Administration] (The changed portion is underlined.)	1. Infection For adults, usually 0.5 to 1 g (potency) of Meropenem is intravenously infused for 30 minutes or longer in two to three divided doses per day. The dosage should be adjusted

according to the patient's age and symptoms and can be increased to 3g (potency) per day with a ceiling of 1 g (potency) per time in patients with severe/refractory infection.
For children, usually 30 to 60 mg (potency)/kg of meropenem is intravenously infused for 30 minutes or longer in three divided doses per day. The dosage should be adjusted according to the patient's age and symptoms and can be increased to 120 mg (potency)/kg per day in children with severe / refractory infection. The dosage should not exceed the maximum daily dose of 3 g (potency) for adults.

2. Febrile neutropenia

(Description omitted because of no change)

[Manufacturer and Distributor] Dainippon Sumitomo Pharma Co., Ltd.