June 19, 2009

Dainippon Sumitomo Pharma Co., Ltd.

Acquisition of an additional indication of AmBisome®, a therapeutic agent for systemic fungal infection

Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka, Japan; President: Masayo Tada) has obtained as of June 17 a Japanese approval for an additional indication and new dosing regimen of "AmBisome® 50mg for intravenous drip infusion", a therapeutic agent for systemic fungal infection, relating to treatment of infections caused by *Mucor* species and species of a few other genera as well as treatment of visceral leishmaniasis.

AmBisome®, discovered by Gilead Sciences, Inc. of the U.S., is an agent to mitigate the side-effects of amphotericin B while retaining its efficacy with regard to treatment of fungal infections by intercalating amphotericin B into a liposomal membrane formulation. This agent is sold in 46 countries outside of Japan, including the U.S., the U.K., Germany and France.
In Japan, this agent, developed by the company was launched in June 2006 with indications of "systemic mycosis, respiratory mycosis, fungal meningitis, and disseminated visceral mycosis caused by *Aspergillus* species, *Candida* species or *Cryptococcus* species" and "febrile neutropenia suspected to be caused by fungal infection".

As a result of the additional indication, this agent can be more widely used than ever to cure systemic mycosis due to addition of *Mucorymycosis*, *Histoplasmosis* and a few others to the three major kinds of fungus covered by the previously approved indication. Cases of infections by imported fungus such as *Histoplasmosis* are feared to increase in number as international intercommunion becomes more active in the future.

Visceral leishmaniasis can be treated by AmBisome® under the newly added indication, though the same has already been allowed outside of Japan. Visceral leishmaniasis is a zoonotic infection of protozoal origin prevalent in the semitropical-to-tropical zone. There is no approved drug in Japan. This agent is thought to be an extremely important medicine as a means to cure visceral leishmaniasis particularly because of its actual medical achievements overseas.

The company expects that as a result of the additional indication and new dosing regimen AmBisome® will be able to meet the needs in medical practice more than before and contribute to furtherance of medical services.

[Please see the separate sheet for an outline of AmBisome®.]

(Reference)

Profile of "AmBisome® for Intravenous Drip Infusion 50 mg"

[Brand name]	AmBisome® for Intravenous Drip Infusion 50 mg
[Generic Name]	Amphotericin B
[Indications] (The underline indicates the added part.)	1.Fungal infections The following infections caused by *Aspergillus* species, *Candida* species or *Cryptcoccus* species, *Mucor* species, *Absidia* species, *Rhizopus* species, *Rhizomucor* species, *Cladosporium* species, *Cladophialophora* species, *Fonsecaea* species, *Phialophora* species, *Exophiala* species, *Coccidioides* species, *Histoplasma* species, and *Blastomyces* species: Systemic mycosis, respiratory mycosis, fungal meningitis, and disseminated visceral mycosis 2. Febrile neutropenia suspected to be caused by fungal infection 3. Visceral Leishmaniasis
[Dosage and Administration] (Addition only)	3. Visceral Leishmaniasis A dose of 2.5 mg (potency)/kg (body weight) of amphotericin B is administered once daily on 1st day -5th day, 14th day and 21st day by intravenous drip infusion over 1-2 hours to a patient with normal immune capacity. In the case of an immunodeficient patient, a dose of 4.0 mg (potency)/kg (body weight) of amphotericin B is administered once daily on 1st -5th day, 10th day, 17th day, 24th day and 38th day by intravenous drip infusion over 1-2 hours.
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma Co., Ltd.