

June 15, 2006

For immediate release

Dainippon Sumitomo Pharma Co., Ltd.

**Launch of AmBisome® 50 mg for Intravenous Drip Infusion,  
a Therapeutic Agent for Systemic Fungal Infection**

Dainippon Sumitomo Pharma Co., Ltd. (DSP) announces the upcoming launch on June 20 of “AmBisome® 50 mg for Intravenous Drip Infusion”, a sterile, non-pyrogenic lyphosized product containing 50 mg of amphotericin B intercalated into a liposomal membrane formulation for injection (hereinafter known as “AmBisome®”) a therapeutic agent for systemic fungal infection and empirical therapy for presumed fungal infection in febrile neutropenic patients.

AmBisome® was developed to mitigate the side effects of amphotericin B while retaining its efficacy with regard to the treatment of fungal infections. In particular AmBisome®'s liposomal formulation provides for a better safety and tolerability profile as compared to non-encapsulated amphotericin B. This is especially true in that AmBisome® is associated with a significantly less risk of renal toxicity (a noted side effect of non-encapsulated amphotericin B), which is believed to be due in part to the lipid bilayer of AmBisome® which encloses the amphotericin B, and also to reduced distribution to the kidneys themselves. Upon intravenous infusion, the liposomal bilayer formulation of AmBisome® provides a unique stable delivery system by adhering to, and targeting fungal cells in the body where upon amphotericin B is released, providing antifungal activity.

AmBisome®, licensed from Gilead Sciences, Inc., is sold in 45 countries outside of Japan, including the United States, the United Kingdom, Germany and France.

AmBisome® has the following features:

1. Liposomal formulation of amphotericin B helps lower the incidence of side effects affecting the kidneys and other organs while retaining the efficacy of amphotericin B.
2. AmBisome® is the only systemic anti-fungal agent for systemic fungal infection with the additional indication of empirical therapy for presumed fungal infection in febrile neutropenic patients approved in Japan.

Through this launch of AmBisome®, DSP is confident that it will contribute significantly to the treatment of diagnosed systemic fungal infection and the treatment of febrile neutropenia suspected to be caused by fungal infection.

For more information, please contact:

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(Reference)

Profile of “AmBisome<sup>®</sup> for Intravenous Drip Infusion 50 mg”

[Brand Name] AmBisome<sup>®</sup> for Intravenous Drip Infusion 50 mg

[Generic Name] Amphotericin B

[Content per Vial] Each vial includes lyophilized product containing 50 mg (potency) of Amphotericin B for intravenous infusion

[Indications]

1. Fungal infections  
The following infections caused by *Aspergillus* species, *Candida* species or *Cryptococcus* species:  
Systemic mycosis, respiratory mycosis, fungal meningitis, and disseminated visceral mycosis
2. Febrile neutropenia suspected to be caused by fungal infection

[Dosage and Administration]

1. Fungal Infections

A dose of 2.5 mg (potency)/kg (body weight) of amphotericin B is administered once daily by intravenous drip infusion over 1–2 hours.

The dosage can be adjusted depending on the patient’s symptoms, but the total daily dose should not exceed 5 mg (potency)/kg (body weight). In the case of patients with cryptococcal meningitis, the daily dosage may be increased up to 6 mg (potency)/kg (body weight).

2. Febrile neutropenia suspected fungal infections

A dose of 2.5 mg (potency)/kg (body weight) of amphotericin B is administered once daily by intravenous drip infusion over 1–2 hours.

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

[Date of Approval] April 20, 2006

[Date of Listing in the NHI reimbursement price] June 1, 2006

[NHI reimbursement price] 50 mg/1 vial: ¥9,958

[Packaging] AmBisome<sup>®</sup> Intravenous Drip Infusion 50 mg: One vial (one filter included)