

May 7, 2008

## **Mycamine<sup>®</sup> Has Now Been Approved in Europe**

Japan, May 7, 2008 - Astellas Pharma Inc. (headquarters: Tokyo, president and CEO: Masafumi Nogimori, "Astellas") today announced that Astellas's European subsidiary has obtained a European approval by the European Medicines Agency (EMA) for Mycamine<sup>®</sup> (generic name: micafungin sodium) on April 25, 2008 (local time).

Astellas's European subsidiary submitted a Marketing Authorization Application (MAA) under the centralized procedure to EMA for Mycamine. The Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending granting a marketing authorization for Mycamine on February 21, 2008, and following this positive opinion, the European Commission has now formally approved Mycamine across the EU.

The indications for adults, adolescents  $\geq 16$  years of age and elderly are: Treatment of invasive candidiasis; Treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate; Prophylaxis of *Candida* infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count  $< 500$  cells /  $\mu$  L) for 10 or more days. For children (including neonates) and adolescents  $< 16$  years of age, Mycamine is indicated for: Treatment of invasive candidiasis; Prophylaxis of *Candida* infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count  $< 500$  cells /  $\mu$  L) for 10 or more days.

Astellas's European subsidiaries plan to launch Mycamine initially in the U.K. and to make Mycamine available across the European market shortly after this.

Mycamine has been available since December 2002 in the Japanese market with the brand name of Funguard<sup>®</sup> for Infusion, where it has established its therapeutic efficacy against fungal infections caused by *Aspergillus* and *Candida* and safety through all therapeutic results. MYCAMINE<sup>®</sup> has been available in the US market since May 2005 and is now indicated for: Treatment of patients with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses; Treatment of patients with esophageal candidiasis; Prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation. Mycamine is available in China, Taiwan, Hong Kong and Korea. This approval in Europe means that Mycamine/Funguard will be available in the US, Asia and Europe and Astellas is expecting that Mycamine will be a new option for the treatment of *Candida* infections throughout Europe. Astellas is committed to develop a franchise in infectious diseases, and this approval in Europe will be a driving force to accelerate this franchise.

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