

September 3, 2007

## **Astellas Announces the Extension of US Regulatory Review for the sNDA of MYCAMINE®**

Japan, September 3, 2007 - Astellas Pharma Inc. (headquarters: Tokyo, President and CEO: Masafumi Nogimori, "Astellas") today announced that its US subsidiary, Astellas Pharma US, Inc. ("Astellas US") has received notification from the U.S. Food and Drug Administration (FDA) that the action date under the Prescription Drug User Fee Act (PDUFA) for the Supplemental New Drug Application (sNDA) seeking approval for the use of its echinocandin MYCAMINE (micafungin sodium) for injection in the treatment of candidemia and other *Candida* infections has been extended by three months.

Astellas US submitted the sNDA to the FDA in December 2006. It was initially scheduled to receive the action letter in October 2007. The FDA has notified Astellas US that the review will be extended by three months in order to allow sufficient time to review additional information recently submitted by Astellas US in response to FDA requests.

MYCAMINE has been commercially available in the US market since May 2005 for the treatment of patients with esophageal candidiasis and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation. Astellas is expecting to contribute more to the treatment of fungal infections as a result of the addition of this supplemental indication once approved. MYCAMINE has been available in the domestic market with the brand name of Funguard® for Infusion since December 2002. Funguard for Infusion has established its therapeutic efficacy against fungal infections caused by *Aspergillus* and *Candida* and safety through therapeutic results.

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