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**ASTELLAS PHARMA US, INC. SUBMITS SUPPLEMENTAL NEW DRUG APPLICATION  
FOR ANTIFUNGAL PRODUCT MYCAMINE®**

*Submission of additional indication supports Astellas' commitment to the Infectious Disease community*

**Deerfield, Illinois, December 26, 2006** - Astellas Pharma US, Inc. announced today that, on December 21, 2006, they submitted a Supplemental New Drug Application (sNDA) to the Food and Drug Administration (FDA) seeking approval for the use of its echinocandin MYCAMINE® (micafungin sodium) for injection in the treatment of candidemia and other *Candida* infections. In 2005, MYCAMINE received approval by the FDA for the treatment of patients with esophageal candidiasis and prophylaxis of *Candida* infection in patients undergoing hematopoietic stem cell transplantation.

"Astellas has had a strong presence in the anti-fungal market for several years and continues to invest in discovering new ways to address the therapeutic needs of clinicians and their patients," said Yoshihiko Hatanaka, President and Chief Executive Officer, Astellas Pharma US, Inc. "With this new submission, we continue our commitment to the infectious disease community and look forward to working with the FDA to bring this potential new treatment option to patients."

### **About Candidemia**

Invasive candidiasis is a fungal infection that occurs when *Candida* species enter the blood, causing bloodstream infection and then spreading throughout the body.

According to the Center for Disease Control (CDC), candidemia is the fourth most common bloodstream infection among hospitalized patients in the United States. A survey conducted at CDC found that candidemia occurs in 8 of every 100,000 persons per year. Persons at high risk for candidemia include low-birth-weight babies, surgical patients, and those whose immune systems are deficient.<sup>1</sup>

### **About MYCAMINE**

**MYCAMINE** (micafungin sodium) for injection is an echinocandin – a newer class of antifungal agents. **MYCAMINE** inhibits an enzyme essential for fungal cell-wall synthesis and is fungicidal (lethal) for *Candida*. **MYCAMINE** can be used concomitantly with a variety of other drugs, including the HIV protease inhibitor ritonavir and the transplant medications cyclosporine and tacrolimus.

### **Important Safety Information**

MYCAMINE is contraindicated in patients with hypersensitivity to any component of this product.

Isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock) have been reported in patients receiving MYCAMINE.

## News Release

Isolated cases of clinically significant hepatic dysfunction, hepatitis, worsening hepatic failure, renal dysfunction, acute renal failure, hemolysis, or hemolytic anemia have occurred in some patients who have received MYCAMINE. Patients who develop these conditions, or abnormal liver or renal function tests, should be monitored for worsening function and evaluated for risk/benefit of continuing MYCAMINE therapy.

Adverse events with MYCAMINE included mental confusion and possible histamine-mediated symptoms (including rash, pruritus, facial swelling, and vasodilatation).

### **About Astellas Pharma US, Inc.**

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a US affiliate of Tokyo-based Astellas Pharma Inc., Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global pharmaceutical company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. For more information about Astellas Pharma US, Inc., please visit our website at [www.astellas.com/us](http://www.astellas.com/us).

<sup>1</sup><http://www.cdc.gov/ncidod/dbmd/diseaseinfo/> - accessed 12/19/2006