

Media Contacts: Maribeth Landwehr
847-317-8988
maribeth.landwehr@us.astellas.com

FDA APPROVES ADDITIONAL INDICATION FOR ASTELLAS' MYCAMINE®

Deerfield, Illinois, January 22, 2008 - Astellas Pharma Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved their Supplemental New Drug Application (sNDA) seeking approval for the use of MYCAMINE® (micafungin sodium) for Injection in the treatment of patients with Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses. MYCAMINE was approved in 2005 for the treatment of patients with esophageal candidiasis and is the only echinocandin approved for the prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation.

"The FDA's approval of this sNDA further confirms the safety and efficacy profile of MYCAMINE and its importance in the treatment of candidemia and other *Candida* infections," said Yoshihiko Hatanaka, President and Chief Executive Officer, Astellas Pharma US, Inc. "The approval of this additional indication is another step toward fulfilling our mission to provide innovative treatments such as MYCAMINE to help patients with significant medical needs."

About Candidemia

Candidemia is a fungal infection that occurs when *Candida* species enter the blood, causing bloodstream infection with the potential to spread to another part of 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 surgical patients, and those whose immune systems are deficient.

About MYCAMINE

MYCAMINE is a member of a newer class of antifungal agents, the echinocandins. MYCAMINE inhibits an enzyme essential for fungal cell-wall synthesis and is fungicidal (lethal) for *Candida*.

MYCAMINE is approved for the treatment of patients with Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses; for the treatment of patients with Esophageal Candidiasis and the prophylaxis of *Candida* Infections in patients undergoing Hematopoietic Stem Cell Transplantation. The efficacy of MYCAMINE against infections caused by fungi other than *Candida* has not been established. MYCAMINE has not been adequately studied in patients with endocarditis, osteomyelitis and meningitis due to *Candida* infections.

MYCAMINE can be used concomitantly with a number of other drugs, including the HIV protease inhibitor ritonavir and the transplant medications cyclosporine and tacrolimus with no alteration in the pharmacokinetics of MYCAMINE. Patients should be monitored for sirolimus, nifedipine or itraconazole toxicity if receiving these drugs in combination with MYCAMINE and their dosage reduced, if necessary.

MYCAMINE is available in two sizes, 50mg vial and 100mg vial, offering clinicians convenience of use in the administration of the drug, while reducing waste in the hospital setting.

Important Safety Information

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

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

Isolated cases of clinically significant hepatic dysfunction, hepatitis, 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 histamine-mediated symptoms (including rash, pruritus, facial swelling, and vasodilatation). The most common treatment-emergent adverse events include diarrhea, nausea, vomiting, pyrexia, hypokalemia, thrombocytopenia and headache.

About Astellas Pharma US, Inc.

Astellas Pharma US, Inc., located in Deerfield, Illinois, is a U.S. 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 category leader in focused areas by combining outstanding R&D and marketing capabilities. In the U.S., Astellas markets products in the areas of immunology, urology, anti-infectives, cardiovascular and dermatology. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.com/us.

###