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FDA Approves Pediatric Indication for Astellas' MYCAMINE® (micafungin sodium) for Injection

Northbrook, Ill., June 24, 2013 - Astellas Pharma US, Inc. ("Astellas"), a U.S. subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503), announced that the U.S. Food and Drug Administration (FDA) has approved its Supplemental New Drug Application (sNDA) for the use of MYCAMINE® (micafungin sodium) for injection by intravenous infusion for the treatment of pediatric patients four months and older with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses, esophageal candidiasis, and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplants (HSCT).

"We are pleased with FDA's approval of MYCAMINE for use in pediatric patients four months and older," said Sef Kurstjens, M.D., chief medical officer, Astellas Pharma, Inc. "This expanded indication supports the safety and efficacy of MYCAMINE and delivers on our mission to provide treatments that can help to improve patient care."

"*Candida* infections are a significant concern to pediatric healthcare professionals, and there are limited treatment options," said Antonio C. Arrieta, M.D., Director Pediatric Infectious Diseases, Children's Hospital of Orange County and Clinical Professor, Pediatrics, University of California, Irvine. "Because MYCAMINE has been shown to be safe and effective in treating candidemia in many adult patients, it is an important new option for treating *Candida* infections in pediatric patients age four months and older."

Safety and effectiveness of MYCAMINE in pediatric patients four months and older have been demonstrated based on the evidence from adequate and well-controlled studies in adult and pediatric patients and additional pediatric pharmacokinetic and safety data. Two randomized, double-blind, active controlled studies investigated the safety and efficacy of MYCAMINE in both adult and pediatric patients: one for the treatment of invasive candidiasis and candidemia, and the other for prophylaxis of *Candida* infections in patients undergoing HSCT. Safety and effectiveness of MYCAMINE in patients younger than four months of age have not been established.

The overall safety of MYCAMINE was assessed in 479 patients, ages three days through 16 years, who received at least one dose of MYCAMINE in 11 separate clinical trials. The mean treatment duration was 24.8 days. In all pediatric studies with MYCAMINE, 439 of 479 (92%) patients experienced at least one treatment-emergent adverse reaction. The most common (≥15%) TEAEs observed in all MYCAMINE-treated pediatric patients age four months and older were: vomiting (31%), diarrhea (22%), pyrexia [fever (22%)], nausea (19%), abdominal pain (16%) and thrombocytopenia [low blood platelet levels (15%)].

MYCAMINE dosage in pediatric patients age four months and older is as follows:

Indication	Pediatric Dose Given Once Daily	
	30 kg or less	Greater than 30 kg
Treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses	2 mg/kg (maximum daily dose 100 mg)	
Treatment of Esophageal Candidiasis	3 mg/kg	2.5 mg/kg (maximum daily dose 150 mg)
Prophylaxis of *Candida* Infections in HSCT Recipients	1 mg/kg up to 50 mg	

About *Candida* and *Candida* Infections
Candida is a type of yeast that causes common fungal infections. *Candida* normally lives on the skin without illness, however, overgrowth and compromised immune systems can lead to symptoms of infection. Candidemia occurs when *Candida* enters the bloodstream, which can lead to spread of the infection to other parts of the body.

Candida species are the third most common cause of pediatric health care associated bloodstream infection.

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

Indications and Usage:

MYCAMINE is indicated in adults and pediatric patients four months and older for:

- Treatment of patients with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses.
  - Mycamine has not been adequately studied in patients with endocarditis, osteomyelitis and meningitis due to *Candida* infections
- Treatment of patients with esophageal candidiasis
- Prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation
  - NOTE: The efficacy of MYCAMINE against infections caused by fungi other than *Candida* has not been established.

MYCAMINE was approved in 2005 for the treatment of adult patients with esophageal candidiasis and in 2008 for use in adult patients with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses. MYCAMINE is the only echinocandin antifungal agent approved for the prophylaxis of *Candida* infections in adult, and now pediatric, patients undergoing HSCT.

Important Safety Information for MYCAMINE® (micafungin sodium) for Injection

MYCAMINE is contraindicated in patients with known hypersensitivity to micafungin sodium, any component of MYCAMINE, or other echinocandins.

Isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock) have been reported in patients receiving MYCAMINE. In these cases, MYCAMINE should be discontinued and administer appropriate treatment.

Elevations in BUN and creatinine, 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 closely for worsening function and evaluated for risk/benefit of continuing MYCAMINE therapy.

In clinical trials, possible histamine-mediated symptoms have been reported with MYCAMINE (including rash, pruritus, facial swelling, and vasodilatation).

In clinical trials, the most common treatment-emergent adverse reactions in adults for all indications included diarrhea, nausea, vomiting, pyrexia, thrombocytopenia, and headache. The most common treatment-emergent adverse reactions observed in pediatric patients four months and older included vomiting, diarrhea, pyrexia, nausea, abdominal pain and thrombocytopenia.

Please see complete Prescribing Information for MYCAMINE.

About Astellas Pharma US, Inc.
Astellas Pharma US, Inc., located in Northbrook, 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. For more information about Astellas Pharma US, Inc., please visit our website at www.astellas.us.

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MEDIA CONTACT

Jenny Kite, Astellas
(847) 682-4530 cell
Jenny.Kite@astellas.com