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FDA approves sNDA for Astellas's antifungal drug

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U.S. FDA approves supplemental new drug application (sNDA) for expanded indication of MYCAMINE®

Japan based Astellas Pharma Inc. has announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental New Drug Application (sNDA) for MYCAMINE® (micafungin for injection) in support of the treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.

With the approval, MYCAMINE is the first antifungal drug approved in the United States specifically for the treatment of invasive candidiasis for this patient population. Candidiasis in newborns is associated with 20 percent mortality and significant morbidity and mortality in infants.[i] MYCAMINE was approved for adults for *Candida* infections in 2005, and in 2013 for pediatric patients aged four months and older.

"Although rare, invasive candidiasis in newborns constitutes a unique pathogenesis unlike that demonstrated in older children and adults as marked by a higher incidence of organ involvement, especially in the central nervous system," said Laura Kovanda, Ph.D, Senior Director, Global Development Project Leader, Infectious Diseases and Oncology, Astellas. "We're pleased with this decision and the potential benefits MYCAMINE may offer to young infants and their families impacted by invasive candidiasis."

The safety of MYCAMINE was assessed in 168 pediatric patients younger than 4 months of age who received varying doses of MYCAMINE in nine clinical trials.

The approved dose for MYCAMINE in neonates and young infants less than four months is 4 mg/kg once daily.