

Health Canada approves Astellas' Mycamine®

A new anti-fungal treatment for Candida infections in immunocompromised patients

Markham, Ontario, June 2007 - Mycamine® (micafungin sodium for injection) has been approved by Health Canada for the treatment of esophageal candidiasis and the prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation. Mycamine, manufactured by Astellas Pharma Inc. and marketed by Astellas Pharma Canada, Inc., is expected to be available in September 2007. ¹

Mycamine belongs to a new class of anti-fungal agents, the echinocandins, which inhibit cell wall synthesis. Specifically, Mycamine blocks the synthesis of 1,3-β-D-glucan, an integral fungal cell wall component. Fungal infections are often a prevalent complication for patients undergoing cancer treatment as a result of immune suppression with patients developing granulocytopenia. ¹ Mycamine is the first echinocandin to be approved for prophylaxis of Candida infections.

The approval of Mycamine is based on 32 clinical studies conducted in the United States, Canada, Japan, South America, Europe and Africa. The clinical development program included data from 2,402 subjects. Subjects in the Mycamine studies included a broad range of individuals who had a confirmed, or were at risk for, candida fungal infections, including patients with hematologic malignancies, bone marrow transplant recipients and HIV-positive patients. ¹

A randomized, double-blind comparative trial of Mycamine and AmBisome® (liposomal amphotericin B), a cornerstone of treatment and prevention of fungal infections, was recently published in *The Lancet*, May 5, 2007. The international study involved 531 patients, enrolled at 155 sites between 2003 and 2004, who were being treated for candidemia and/or invasive candidiasis.

Results showed that Mycamine was as effective as AmBisome in treating fungal infections. However, Mycamine demonstrated reduced toxicity, with fewer side effects and treatment discontinuation than in patients receiving AmBisome. Amphotericin B, an effective treatment for Candida infections, has been associated with significant side effects including renal dysfunction, infusion related toxicities and electrolyte imbalances. The effect of both treatments was independent of the primary site of the infections and the patient's immune system status, or whether patients had an indwelling catheter.²

"The results of the clinical trials of Mycamine show this medication is effective in preventing or treating opportunistic fungal candida infections in patients, such as those undergoing treatment for certain types of cancer or who are HIV positive." says Barbara Reynolds, Director of Marketing, Astellas Pharma Canada, Inc. "These results are encouraging and we are pleased to be able to offer physicians another option to benefit their patients who may suffer health complications as a result of a fungal infection."

About Mycamine

The novel mechanism of action of echinocandins specifically targets the wall of fungal cells to treat or prevent the infection. Mycamine is contraindicated in patients with hypersensitivity to any component of the product. Patients receiving Mycamine have reported isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock), significant hemolysis and hemolytic anemia. The most common side effects experienced in the clinical trials included changes in liver and renal function. Possible histamine-mediated symptoms have been reported with Mycamine, including rash, pruritus, facial swelling, and vasodilatation. Injection site reactions, including phlebitis and thrombophlebitis, have been reported at Mycamine doses of 50-150 mg/day. ¹



Press Release

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc. is highly focused on customers and their needs and is committed to making a difference in the treatment of infectious diseases. Astellas Pharma Canada is dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. It is one of the Astellas Group of companies in North America and an affiliate of Astellas Pharma Inc., located in Tokyo. The organization is committed to becoming a global pharmaceutical leader by combining outstanding R&D and marketing capabilities. Additional corporate information is available at www.astellas.com/ca.

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AmBisome is a registered trade-mark of Gilead Sciences, Inc., used under license.

For more information and to book interviews contact:

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References

1. Mycamine[®] Product Monograph, Astellas Pharma Canada, April 9, 2007.
2. Kuse ER, Chetchotisakd P, da Cunha CA, Ruhnke M, Barrios C, et al. Micafungin versus liposomal amphotericin B for candidaemia and invasive candidosis: a phase III randomised double-blind trial. *The Lancet* 2007; 369:1519-1527.