

**FOR IMMEDIATE RELEASE**

**HEALTH CANADA APPROVED CANCIDAS® FOR THE EMPIRICAL TREATMENT OF FUNGAL INFECTIONS IN FEBRILE-NEUTROPENIC PATIENTS**

**TORONTO, Ontario – March 8, 2005** — The indication for CANCIDAS® (caspofungin acetate) has been expanded to include empirical therapy for presumed fungal infections in febrile, neutropenic patients. Each year over 7,000 Canadians develop febrile neutropenia<sup>1</sup> — fever accompanied by a very low white blood cell count. Health Canada approval was based on the results of the largest prospective antifungal empirical therapy trial published to date in neutropenic patients with persistent fever. The study was published in the September 30, 2004 issue of *The New England Journal of Medicine* and showed that caspofungin is as effective as and generally better tolerated than the comparator liposomal amphotericin B when given as empirical therapy in patients with persistent fever and neutropenia.<sup>2</sup>

***Important cause of disease and death***

Fungal infections such as candidiasis and aspergillosis are a serious threat to the recovery of very sick patients such as those being treated with chemotherapy for cancer or following a bone marrow transplant.

“Clinical experience has shown that when fever persists in a very sick patient with a very low white blood cell count despite the use of broad spectrum antibiotics, it is likely the patient may be fighting a fungal infection,” said Dr. Coleman Rotstein, Professor of Medicine and Director, Infectious Diseases Residency Training Program at McMaster University, Hamilton. “This indication is good news. Caspofungin was better tolerated than liposomal amphotericin B and significantly improved patients’ survival.”

***Approval based on largest study of its kind<sup>2</sup>***

The multicentre, randomized, double-blind study, which was carried out in over 100 centres in Canada, United States and Europe, is the largest prospective antifungal empirical therapy trial published to date in neutropenic patients with persistent fever.

The study included 1,095 patients over the age of 16 who had received chemotherapy for malignancy or had undergone bone marrow transplant and had been diagnosed with persistent febrile neutropenia and who had been on broad-spectrum antibiotics for at least 96 hours. The primary efficacy variable was a favourable overall response, as determined by a five-component endpoint previously used in other studies of empirical antifungal therapy.

**Study highlights include:**

- Based on the primary endpoint, caspofungin was shown to be as effective as liposomal amphotericin B
- Of those with baseline documented fungal infections, more patients treated with caspofungin (51.9 per cent) than with liposomal amphotericin B (25.9 per cent) had a successful outcome
- Significantly fewer patients who received caspofungin experienced kidney problems, infusion related events, any drug-related adverse events, or discontinued therapy due to a drug-related adverse event
- Patients with baseline fungal infections treated with caspofungin had improved survival

## **Caspofungin – New indication/2**

### **More important information about CANGIDAS®**

A once-daily intravenous medicine, caspofungin is the first and only approved agent in the echinocandin class of antifungals that is currently approved in Canada as a first-line treatment for invasive candidiasis and esophageal candidiasis. In addition to its new indication for the empirical therapy for fungal infections in febrile, neutropenic patients, caspofungin is also approved for the treatment of invasive aspergillosis in patients who do not respond to or who cannot tolerate the other antifungal therapies, i.e., amphotericin B, lipid formulations of amphotericin B and/or itraconazole.

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### **References:**

1. Desjardins B, Meilleur M-C. Department of Health Economics and Outcomes Research, Merck Frosst Canada Ltd. *Epidemiology of Febrile Neutropenia in Canadian Provinces: Hospitalization-Based Incidence*, (poster presentation) 7<sup>th</sup> International Febrile Neutropenia Symposium, January 2005, Spain
2. Walsh T, et al. *Caspofungin versus Liposomal Amphotericin B for Empirical Antifungal Therapy in Patients with Persistent Fever and Neutropenia*, N Engl J Med, September 30, 2004, Vol. 351:1391-1402, Number 14

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