

Fujisawa GmbH Submits New Antifungal Drug in Europe

Munich, 25 February 2003. Fujisawa GmbH announced today that an application for approval of micafungin, a novel antifungal product, has been submitted in Europe on February 17, 2003.

Micafungin belongs to a new class of antifungal agents, the so-called echinocandins that are characterised by a novel mechanism of action targeting the fungi specific pathway of cell wall synthesis.

Patients who are immunocompromised due to cancer chemotherapy, organ or bone marrow transplantation, or human immunodeficiency virus infection are predisposed to severe fungal infections. The increasing use of cytotoxic therapy and transplantation procedures is associated with an increase in the frequency of invasive fungal infections, mainly caused by *Candida* and *Aspergillus* species.

Fujisawa GmbH is seeking approval to use micafungin in patients suffering from invasive fungal infections. The submission includes data from studies conducted in Europe, the United States, South America, Africa, Canada and Japan.

With micafungin, the latest in a series of novel agents from the company's pipeline, Fujisawa confirms its commitment to research and development of innovative compounds for niche markets and strives to strengthen its hospital speciality portfolio.

In Japan, micafungin has been launched under the tradename 'Funguard® for Infusion' in December 2002 and is now recognised there as a drug contributing to the treatment of deep-seated fungal infections. In the U.S., Fujisawa Healthcare, Inc. submitted a New Drug Application (NDA) for micafungin to the Food and Drug Administration (FDA) in April 2002. On January 29, 2003, Fujisawa Healthcare received communications from the FDA regarding the status of the micafungin NDA review and is now working closely with the FDA to meet their requirements for approval. Micafungin has also been filed in Canada since June 2002.

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Fujisawa GmbH, the European Headquarters of Fujisawa Pharmaceutical Co., Ltd., is based in Munich, Germany, with subsidiaries located in all major European countries. Fujisawa Pharmaceutical Co., Ltd., based in Osaka, Japan, was founded in 1894 and is a leading pharmaceutical manufacturer actively developing its international operations in North America, Europe and Asia. Additional information on Fujisawa GmbH can be found on the Company's Website at www.fujisawaeurope.com.