



New Medicines for New Times

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Fujisawa Updates the European Development Status of Micafungin

Japan, September 3, 2004 - Fujisawa Pharmaceutical Co., Ltd., today announced that it now expects the approval of its injectable candidin antifungal agent micafungin in Europe to be in the first half of 2006 because additional data have been requested.

Fujisawa GmbH, a wholly owned subsidiary of the Company, submitted the application for approval to use micafungin in patients suffering from invasive fungal infections via centralized procedure to the European Medicines Agency (EMA) in February 2003. Based on the discussion with the EMA, however, Fujisawa decided to submit additional data for approval. As Fujisawa plans to sequentially submit additional data from spring 2005, the Company now expects the first approval of micafungin will be in the first half of 2006. Fujisawa has changed the European development status of micafungin to "to be filed" because the European review process does not allow for submission of additional data to supplement the current application and requires to resubmit the application in combination with new data.

Micafungin has been well accepted in Japanese medical circles as a new option for the treatment of the deep-seated fungal infections since its launch in December 2002 from the medical society. Additional indication of micafungin for pediatric use was filed in Japan in July this year. Micafungin is also under review in the U.S.

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