Fujisawa launches the candin antifungal agent, Funguard® for Infusion

Japan, December 6, 2002 - Fujisawa Pharmaceutical Co., Ltd., today announced the launch of the candin antifungal agent, Funguard® for Infusion (generic name: micafungin sodium), in Japan on December 6, 2002. Funguard® is indicated for various infections caused by *Aspergillus* and *Candida* such as fungemia, respiratory mycosis and gastrointestinal mycosis.

The number of immunocompromised patients, who are highly susceptible to life-threatening fungal infections, is growing as more patients undergo bone marrow, stem cell and solid organ transplants as well as chemotherapy for cancer. Invasive fungal infections carry a substantial morbidity and mortality in immunocompromised patients, however currently available drugs for treatment are limited in success because of their lack of broad-spectrum fungicidal activity and/or undesirable toxicities. Therefore, there is a need for safe and highly efficacious antifungal agents for the treatment of invasive fungal infections.

Fujisawa has focused on interfering effectively with fungal cell wall biosynthesis by selective inhibition of (1, 3)-β-D-glucan synthase, since (1,3)-β-D-glucan is an essential component of the skeletal structure of the fungal cell wall that is absent in mammalian cells. Fujisawa’s intensive research has succeeded in creating and developing Funguard®, the first candin in Japan, which belongs to an entirely new class of antifungal agents. Funguard® exhibits potent antifungal activity against the two major opportunistic fungal pathogens, *Candida* and *Aspergillus*. The agent possesses fungicidal effect against *Candida* species and inhibits the growth of *Aspergillus* species by inhibiting the budding of fungal cells and bursting the apical region of buds.

Funguard® has been developed worldwide by Fujisawa and its clinical study data has shown its significant treatment success against systemic Candidiasis and Aspergillosis and safety profile. Fujisawa filed an NDA with the Ministry of Health, Labor and Welfare (MHLW) in Japan in June 2001 and received approval from the Agency in October 2002, followed by its listing on the National Health Insurance (NHI) drug price list today.
Funguard® has been granted a “premium for innovativeness” for its NHI drug price because of its novelty and great usefulness for medical care. Funguard® is the third drug receiving the premium in Japan, which means Fujisawa is honored to have received two out of the only three premiums given so far in Japan, following Japan’s first “premium for innovativeness” to the immunosuppressant Prograf®. Fujisawa filed an NDA for micafungin sodium with the Food and Drug Administration in the U.S. in April 2002 and in Canada in June 2002, and is preparing for filing in Europe.

Funguard® is a promising product satisfying unmet medical needs and is expected to contribute to the treatment of invasive fungal infections. Fujisawa will transmit accurate information on the drug to medical institutions for the safe and appropriate use of the agent.

Additional information for Funguard® for Infusion is mentioned as follows;

[PRODUCT NAME]  Funguard® for Infusion 50mg, Funguard® for Infusion 75mg

[REIMBURSEMENT PRICE]  7,618 yen for 50mg, 11,104 yen for 75mg

[DOSAGE AND ADMINISTRATION]

- **Aspergillosis:**
  
  For adults, the usual single dose is 50 - 150 mg (potency) of micafungin sodium and should be infused intravenously once daily. The dosage may be increased up to 300 mg (potency)/day for severe or intractable aspergillosis.

- **Candidiasis:**
  
  For adults, the usual single dose is 50 mg (potency) of micafungin sodium and should be infused intravenously once daily. The dosage may be increased up to 300 mg (potency)/day for severe or intractable candidiasis.

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