

FDA Approves AmBisome® for the Treatment of Cryptococcal Meningitis in AIDS Patients

July 5, 2000 4:33 PM ET

Fujisawa and Gilead Drug Becomes First Lipid Agent Approved for Indication

Deerfield, IL and Foster City, CA -- July 5, 2000

Fujisawa Healthcare, Inc. and Gilead Sciences, Inc. (Nasdaq: GILD) announced that the U.S. Food and Drug Administration (FDA) approved the antifungal drug AmBisome® [(amphotericin B) liposome for injection] for the treatment of cryptococcal meningitis in HIV-infected patients. Fujisawa submitted a supplemental New Drug Application (sNDA) for AmBisome in July 1999 seeking a label expansion for the additional indication.

“The FDA’s approval of this submission makes AmBisome the first lipid agent to receive an indication for cryptococcal meningitis in HIV-infected patients,” stated Noboru Maeda, chairman and chief executive officer of Fujisawa. “This is a significant approval for Fujisawa as we strive to become the best in the therapeutic class.”

Cryptococcal meningitis, a life-threatening infection of the membranes that line the brain and spinal cord (meninges), can occur when a patient is exposed to the fungus *Cryptococcus neoformans*. The organism can infect almost all organs in the body, although it most commonly causes disease of the meninges, skin, or lungs. The majority of people with cryptococcal meningitis have immune systems that are damaged by disease, such as AIDS, or suppressed by drugs. Cryptococcal meningitis is the most common cryptococcal infection in people infected with HIV, affecting 5-10 percent of these patients.

In February, the FDA approved a labeling supplement for AmBisome that provided data comparing the safety of AmBisome with Abelcet® (amphotericin B lipid complex, produced by The Liposome Company). As a result, the AmBisome label now includes a claim of superior safety compared to Abelcet in febrile neutropenic cancer patients. Despite the fact that those patients in the clinical trial who received AmBisome had significantly less nephrotoxicity, dose-limiting renal toxicity may still be observed with AmBisome.

About AmBisome®

AmBisome is a unilamellar (single-layer) liposomal formulation of amphotericin B and is the only true liposomal formulation of this standard of therapy for systemic antifungal therapy. AmBisome is indicated for empirical therapy (treatment based upon the clinical symptoms of a patient, rather than the results of culture tests) for presumed fungal infection in febrile, neutropenic patients; in patients with *Aspergillus* species, *Candida* species and/or *Cryptococcus* species infections refractory (non-responsive) to conventional amphotericin B; and for the treatment of visceral leishmaniasis. Additionally, AmBisome is recommended for the treatment of patients where renal impairment or unacceptable toxicity suggests that conventional amphotericin B should not be used or should be discontinued.

About Fujisawa and Gilead

Fujisawa Healthcare, Inc., headquartered in Deerfield, IL, develops, manufactures, and markets proprietary pharmaceutical products in the United States and abroad. Fujisawa Healthcare, Inc. is a subsidiary of Fujisawa Pharmaceutical Co., Ltd., based in Osaka, Japan. Fujisawa Pharmaceutical Co., Ltd., founded in 1894, is a leading pharmaceutical manufacturer with international operations in North America, Europe, and Asia. Additional information on Fujisawa Healthcare, Inc. and its products can be found on the Internet at www.fujisawa.com.

Gilead Sciences, headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK; and Dublin, Ireland and sales and marketing organizations in the United States, Europe, and Australia. For more information about Gilead, visit the Company's Web site at www.gilead.com.