New AmBisome® Label Includes Claim Of Superior Safety Profile Compared To Abelcet® In Febrile Neutropenic Cancer Patients

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Fujisawa Healthcare and Gilead Sciences announce FDA approval of sNDA

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Fujisawa Healthcare, Inc. and Gilead Sciences, Inc. (Nasdaq:GILD) announced today that the Food and Drug Administration (FDA) has approved a supplemental new drug application for AmBisome® (amphotericin B) liposome for injection. The label for AmBisome will now include comparative data from a multi-center, randomized, double-blind trial that assessed the safety of AmBisome (co-marketed by Fujisawa Healthcare, Inc. and Gilead Sciences, Inc.) and Abelcet® (amphotericin B lipid complex), manufactured by The Liposome Company.

In the trial, AmBisome was demonstrated to be significantly safer than Abelcet in the management of potentially life threatening fungal infections in neutropenic cancer patients. The trial was conducted at 18 major cancer treatment centers in the United States and involved 244 patients.

“Managing fungal infection while minimizing damage to the kidney is often a delicate task. We are dealing with very sick patients, and that is why knowing which drug has the better safety profile is so important to us,” said Dr. Pablo J. Cagnoni, assistant professor of medicine in the bone marrow transplant program at the University of Colorado and an investigator in the clinical trial. “Although both products contain amphotericin B, differences in their chemical composition and physical form of the lipid component seems to affect their functional properties.”

In the trial, only 14.5 percent of AmBisome patients had an increase in serum creatinine of two times baseline, compared to 42.3 percent among Abelcet patients (serum creatinine is a laboratory marker of nephrotoxicity). Despite the fact that patients who received AmBisome observed significantly less nephrotoxicity than those who received Abelcet, dose-limiting renal toxicity may still be observed with AmBisome.

“This is the only trial in which these agents have been compared in a prospective, randomized, double-blind fashion, which represents the highest standard for trial design,” stated Dr. Ira Lawrence, senior vice president, research and development at Fujisawa Healthcare, Inc.

Neutropenic patients with unresolved fever after three days of antibacterial therapy were randomized (1:1:1) to receive either Abelcet 5 mg/kg/day (n=78), AmBisome 3 mg/kg/day (n=85), or AmBisome 5mg/kg/day (n=81). There was no difference in efficacy or safety between the two AmBisome groups, and both were significantly safer than the Abelcet group.

The trial also showed that patients who received AmBisome (3 mg/kg/day or 5mg/kg/day) had a statistically lower incidence of infusion-related reaction including chills, hypertension, hypotension, tachycardia, and hypoxia than those administered Abelcet (5mg/kg/day).

“A greater number of patients receiving Abelcet had to discontinue the drug prematurely due to toxicity, as compared to the AmBisome patients,” said Dr. Elias Anaissie, professor of medicine and chief, Section of Supportive Care and Oncology Emergencies, University of Arkansas Medical Sciences Center, Little Rock, and an investigator in the trial. “We use these lipid forms because our patients are not able to tolerate conventional amphotericin B. Being able to keep more patients safely on AmBisome therapy is a great benefit for us and the patient.”

Commenting on the trial results, Noboru Maeda, chairman and chief executive officer of Fujisawa Healthcare, Inc., said that “AmBisome has enjoyed significant growth since being launched in the United States two years ago. We are pleased to be able to offer physicians an effective and safer treatment alternative for these often-fatal infections, and the FDA’s decision to include this new data in our label further differentiates AmBisome from other therapies for fungal infections.”

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 and is actively developing its 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.