Pharmacoeconomic Study Compares Total Hospital Costs of AmBisome® to Abelcet® for Empirical Treatment of Patients with Febrile Neutropenia

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Data presented at 40th ICAAC

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Fujisawa Healthcare, Inc. (FHI) and Gilead Sciences, Inc. (Nasdaq: GILD) today announced the results of a pharmacoeconomic study comparing the use of AmBisome (amphotericin B) liposome for injection to that of Abelcet® (amphotericin B lipid complex) in the empirical treatment of persistently febrile neutropenic patients with presumed fungal infection. Researchers concluded that nephrotoxicity is associated with higher hospital costs and increases the likelihood of renal dialysis. In this study, AmBisome 3mg/kg/day was found to be more cost-effective than Abelcet 5mg/kg/day due to a significant reduction in treatment-related nephrotoxicity.

Results of this study were presented by Richard Greenberg, M.D., Professor of Medicine, University of Kentucky, on Sunday, September 17, 2000 at the 40th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Toronto, Canada.

“The reduced incidence of nephrotoxiciy associated with AmBisome for empirical therapy for presumed fungal infections in patients with febrile neutropenia has clear benefits,” said Dr. Greenberg. “Our analyses of hospital and drug costs associated with this therapy further support the cost effectiveness of AmBisome in this patient population.”

Study Design and Methods
This analysis is a sub-study of a randomized, double-blind, multicenter trial comparing two doses of AmBisome (3 mg/kg/day and 5/mg/kg/day) to Abelcet 5 mg/kg/day for empirical therapy for presumed fungal infections in febrile neutropenic patients. The study enrolled 244 patients. Hospital billing data were collected for 89 (36.5 percent) of those patients.

The cost analysis was conducted from the hospital perspective and examined length of stay and costs from the first day of antifungal therapy to hospital discharge for patients receiving either AmBisome or Abelcet. Hospital charges were converted to costs, using an institution-specific ratio of cost to charges for each hospitalization. Drug costs were modeled based on average wholesale price (AWP) and varied as part of a sensitivity analysis.

Results
In both the clinical (n=244) and cost study (n=89) samples, patients treated with Abelcet experienced a higher incidence of nephrotoxicity as defined by a doubling of baseline creatinine – 15.6 percent for AmBisome 3 mg/kg/day vs. 14.8 percent AmBisome 5 mg/kg/day vs. 43.3 percent for Abelcet 5 mg/kg/day ($p<0.05$). Across all treatment groups, hospital costs were higher for patients who developed nephrotoxicity. For patients with no renal toxicity (n=67) the average hospital costs totaled $37,246. For patients with renal toxicity (n=22), the average hospital costs totaled $62,004 ($p<0.05$).

Patients who developed renal toxicity in the cost study sample were more likely to require renal dialysis. Three percent (2/67) of non-nephrotoxic patients required renal dialysis compared to 27 percent (6/22) of patients with renal toxicity ($p<0.05$).

Hospital costs, excluding drug costs, were highest in the renal toxicity and dialysis groups. Of the patients without renal toxicity, the average costs for those who did not require dialysis were $36,879 (n=65) and for patients who did require dialysis (n=2) the average costs totaled $49,161. In the group of patients with renal toxicity, the average costs for patients who did not require dialysis were $45,797 (n=16) and for patients who did require dialysis (n=6) the average costs totaled $105,222.

Using a decision analysis model with nephrotoxicity and renal dialysis as the primary outcomes, it was determined that total average overall hospital costs, including drug costs, in this study were lowest for patients treated with AmBisome at a dose of 3 mg/kg/day ($47,747) compared to Abelcet at 5 mg/kg/day ($52,133) or AmBisome at 5 mg/kg/day ($53,033).

Despite significantly less nephrotoxicity of AmBisome observed at a dose of 3 mg/kg/day compared to Abelcet at a dose of 5 mg/kg/day, dose limiting renal toxicity may still be observed with AmBisome.

About AmBisome
AmBisome is a unilamellar (single-layer) liposomal formulation of amphotericin B. Available in 42 countries worldwide, AmBisome is the only true liposomal formulation of amphotericin B, the standard of care for systemic antifungal therapy. Fujisawa Healthcare and Gilead co-market AmBisome in the United States. The drug is marketed exclusively by Fujisawa in Canada and by Gilead in the remaining 40 countries in which it is available.

AmBisome labels include indications for empirical therapy for presumed fungal infection in febrile, neutropenic patients; Aspergillus species, Candida species and/or Cryptococcus species infections refractory (non-responsive) to conventional amphotericin B; and 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. Product labeling for AmBisome varies in each of the countries in which it is marketed.

In July, the U.S. Food and Drug Administration approved AmBisome as a treatment for cryptococcal meningitis in HIV-infected patients. This approval followed a label expansion earlier in the year to include head-to-head data demonstrating AmBisome's superior safety profile versus Abelcet (amphotericin B lipid complex).

AmBisome has a demonstrated superior safety profile compared to conventional amphotericin B for the empirical treatment of febrile, neutropenic patients. In clinical trials, nephrotoxicity and infusion-related reactions were observed. Side effects associated with the use of AmBisome include, but are not limited to, chills, diarrhea, nausea and vomiting. For full prescribing information for AmBisome, please call 1-800-727-7003 or refer to www.ambisome.com.

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. Gilead 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, IR 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.

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements. Such risks and uncertainties include the risk that these data will not be accepted by the medical community and that these data will not be replicated in clinical practice or in other studies. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 1999 on file with the U.S. Securities and Exchange Commission.