Gilead Sciences and World Health Organization Establish New Five-Year Initiative to Prevent Deaths from Visceral Leishmaniasis

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- Gilead's $8 Million Donation of VL Treatment AmBisome(R) Will Reach 50,000 People in Resource-Limited Countries -

GENEVA, Dec 08, 2011 (BUSINESS WIRE) --

Gilead Sciences, Inc. (Nasdaq:GILD) announced today that it will donate 445,000 vials of AmBisome(R) (amphotericin B liposome for injection) over five years to help the World Health Organization (WHO) treat more than 50,000 patients with visceral leishmaniasis (VL), also known as kala-azar.

Visceral leishmaniasis is widespread in South Asia and the Horn of Africa, where it affects hundreds of thousands of people annually. Without treatment, the mortality rate is close to 100 percent. In the Indian subcontinent, where VL is endemic, the WHO Leishmaniasis Expert Committee recommends single-dose AmBisome as the safest, most effective treatment for the disease. AmBisome is approved for the treatment of VL in the United States.

"This commendable donation means that every AmBisome vial will contribute to saving a life," commented Dr. Jorge Alvar, who heads WHO's Leishmaniasis programme in the Department of Control of Neglected Tropical Diseases. "We hope that this commitment by Gilead will encourage other partners to join the fight in overcoming this neglected tropical disease."

"Gilead is proud to expand our long-standing partnership with WHO," said John C. Martin, PhD, Chairman and Chief Executive Officer of Gilead Sciences. "We continually seek to identify new ways to increase access to our anti-infective therapies, and have the highest regard for WHO's efforts to combat VL worldwide. Working in conjunction with health ministries, WHO will now be able to save more lives by expanding patient access to AmBisome."

Gilead has supported WHO's leishmaniasis control program since 1992. Currently Gilead offers AmBisome through the company's access program at no-profit pricing - or pricing that is at or below Gilead's manufacturing cost - in a number of countries hardest hit by VL. If sold at Gilead's no-profit access price, today's donation would cost more than $8 million. The company also donates AmBisome for use in clinical studies aimed at identifying the most effective VL treatment regimens.

These initiatives are part of the Gilead Access Program, which aims to provide wider access to the company's medications to affected populations in the developing world. The Access Program is currently delivering branded or generic versions of Gilead's HIV therapies to 1.8 million patients in developing countries.

About Visceral Leishmaniasis

Visceral leishmaniasis is transmitted by the bite of sand flies carrying the *Leishmania* parasite. The parasite attacks organs and can cause complications such as fever, weight loss, enlargement of the spleen and liver, and increased vulnerability to other life-threatening infections.

About AmBisome

AmBisome is a liposomal formulation of amphotericin B that is administered by intravenous injection. AmBisome is indicated for empirical therapy for presumed fungal infection in febrile, neutropenic patients; for treatment of cryptococcal meningitis in HIV-infected patients; for treatment of patients with *Aspergillus* species, *Candida* species and/or *Cryptococcus* species infections refractory (non-responsive) to conventional amphotericin B, or in patients where renal impairment or unacceptable toxicity precludes the use of conventional amphotericin B; and for treatment of visceral leishmaniasis.

Research has shown AmBisome to be a safe and effective drug for the treatment of VL due to its therapeutic index and half life, and experts recommend it as a first-line treatment against the disease in many parts of the world. A February 2010 Indian study published in *TheNew England Journal of Medicine* found that a single dose of AmBisome 10mg/kg is safe, effective and significantly less expensive than the 15 infusions of amphotericin B deoxycholate over the course of a 29-day hospitalization.

Based on this trial, WHO in December 2010 published guidelines recommending a single AmBisome 10mg/kg infusion as the preferred first-line treatment for VL on the Indian sub-continent.

Important Safety Product Information About AmBisome

CONTRAINDICATIONS

AmBisome is contraindicated in those patients who have demonstrated or have known hypersensitivity to amphotericin B deoxycholate or any other constituents of the product unless, in the opinion of the treating physician, the benefit of therapy outweighs the risk.

WARNINGS AND PRECAUTIONS

General

Anaphylaxis has been reported with amphotericin B deoxycholate and other amphotericin B containing drugs, including AmBisome. If a severe anaphylactic reaction occurs, the infusion should be immediately discontinued and the patient should not receive further infusions of AmBisome.

As with any amphotericin B-containing product the drug should be administered by medically trained personnel. During the initial dosing period, patients should be under close clinical observation. AmBisome has been shown to be significantly less toxic than amphotericin B deoxycholate; however, adverse events may still occur.

Laboratory Tests

Patient management should include laboratory evaluation of renal, hepatic and hematopoietic function, and serum electrolytes (particularly magnesium and potassium).

Drug Interactions

No formal clinical studies of drug interactions have been conducted with AmBisome.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term studies in animals have been performed to evaluate carcinogenic potential of AmBisome. AmBisome has not been tested to determine its mutagenic potential.

ADVERSE REACTIONS

A clinical study comparing AmBisome to amphotericin B deoxycholate (Study 94-0-002) showed that AmBisome was well tolerated. AmBisome had a lower incidence of chills, hypertension, hypotension, tachycardia, hypoxia, hypokalemia, and various events related to decreased kidney function as compared to amphotericin B deoxycholate. In pediatric patients, AmBisome had a lower incidence of hypokalemia, chills, vomiting, and hypertension as compared to amphotericin B deoxycholate. The percentage of patients who received drugs either for the treatment or prevention of infusion-related reactions (e.g., acetaminophen, diphenhydramine, meperidine and hydrocortisone) was lower in AmBisome-treated patients compared with amphotericin B deoxycholate-treated patients.

In an empirical therapy study (Study 97-0-034), on Day 1, where no premedication was administered, the overall incidence of infusion-related events of chills/rigors was significantly lower for patients administered AmBisome compared with amphotericin B lipid complex. Fever, chills/rigors and hypoxia were significantly lower for each AmBisome group compared with the amphotericin B lipid complex group.

Despite significantly fewer infusion-related reactions, chills, rigors, fever, nausea, vomiting, and cardiorespiratory events may still be seen with AmBisome.

Anaphylaxis has been reported with amphotericin B formulations including AmBisome.

TOXICITY AND DISCONTINUATION OF DOSING

One clinical study (94-0-002) showed a significantly lower incidence of grade 3 or 4 toxicity in the AmBisome group compared with the amphotericin B group. In addition, nearly three times as many patients administered amphotericin B required a reduction in dose due to toxicity or discontinuation of study drug due to an infusion-related reaction compared with those administered AmBisome.

In an empirical therapy study (97-0-034), a greater proportion of patients in the amphotericin B lipid complex group discontinued study drug due to an adverse event than in the AmBisome groups.

OVERDOSAGE

The toxicity of AmBisome due to overdose has not been defined. Repeated daily doses up to 10 mg/kg in pediatric patients and 15 mg/kg in adult patients have been administered in clinical trials with no reported dose-related toxicity.

If overdosage should occur, cease administration immediately. Symptomatic supportive measures should be instituted. Particular attention should be given to monitoring renal function.

Note: Liposomal encapsulation or incorporation into a lipid complex can substantially affect a drug's functional properties relative to those of the unencapsulated drug or non-lipid associated drug. In addition, different liposomal or lipid-complex products with a common active ingredient may vary from one another in the chemical composition and physical form of the lipid component. Such differences may affect the functional properties of these drug products.

Please see full Prescribing Information for AmBisome.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

U.S. full prescribing information for AmBisome is available at www.AmBisome.com.

AmBisome is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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