Gilead Announces Phase I/II Data Insufficient for Marketing Clearance of FORVADE™ Topical Gel to Treat Refractory Herpes in Patients with AIDS

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Gilead Sciences, Inc. (NASDAQ:GILD) announced today that the U.S. Food and Drug Administration (FDA) has determined that data from a placebo-controlled Phase I/II clinical study are not sufficient to support marketing clearance of FORVADE™ (cidofovir gel) for the treatment of refractory herpes simplex virus (HSV) infection in patients with AIDS.

The FDA communicated this determination to Gilead in a letter after reviewing Gilead's New Drug Application (NDA) seeking marketing clearance of FORVADE. Upon review of these data, the FDA recommended that Gilead conduct additional studies to support marketing clearance.

In January 1997, the FDA accepted the FORVADE application for review, representing the Agency's opinion that the application was sufficiently complete to permit a substantive review. The application included safety and efficacy data from a single, Phase I/II placebo-controlled study in 30 AIDS patients with refractory herpes lesions, who were randomly assigned to receive either treatment with FORVADE at one of two dose levels or placebo once daily for five days. During the study, neither patients nor physicians knew if patients were receiving active drug or placebo. At two scientific conferences in 1996, clinical investigators presented data from the Phase I/II study that demonstrated a statistically significant treatment effect with FORVADE versus placebo in the healing of the refractory lesions, cessation of viral shedding and reduction in lesion-associated pain.

"Given the recent advances in the treatment of AIDS and the decreased incidence of AIDS-related opportunistic infections, the treatment of refractory herpes represents a small commercial opportunity, but is still a medically important indication for patients with limited treatment options," said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead. "We therefore plan to work with the FDA to determine what additional information would be necessary for approval. While these discussions are ongoing, we will continue to make FORVADE available through an ongoing expanded access program in the United States."

Refractory HSV

Herpes simplex lesions in patients with AIDS that do not respond to treatment with acyclovir, a standard herpes treatment, may be severely debilitating. Because the immune system of a patient with AIDS has a limited ability to fight viral outbreaks or heal HSV lesions, refractory herpes can be painful, persistent and result in significantly larger lesions than occur in non-HIV infected patients with recurrent herpes infections. While the large majority of patients with AIDS suffering from herpes simplex lesions respond to current treatment options, there are limited treatment alternatives for the small number of patients who develop unresponsive lesions.

Gilead Sciences is a biopharmaceutical company dedicated to the discovery, development and commercialization of treatments for human diseases. The Company's business and scientific endeavors are focused on making new therapies available to patients, physicians and the healthcare system. Gilead's expertise has resulted in proprietary therapeutics for important viral diseases, including a currently available therapy for cytomegalovirus retinitis, and products in development to treat diseases caused by human immunodeficiency virus, hepatitis B virus, herpes simplex virus, human papillomavirus and influenza virus. Gilead's research programs seek treatments for these and other viral infections, vascular diseases and cancer. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.