

Gilead Begins Phase II Clinical Trials of Oral GS 840 for Chronic Hepatitis B

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Earlier Study Demonstrated that GS 840 had Potent Antiviral Activity Against Hepatitis B Virus

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Gilead Sciences, Inc. ([NASDAQ:GILD](#)) announced today that it has begun enrolling patients in two multinational Phase II studies of GS 840 (adefovir dipivoxil) for the potential treatment of chronic hepatitis B virus (HBV) infection.

GS 840 is an oral tablet with demonstrated antiviral activity against a broad spectrum of viruses, including hepatitis B virus, human immunodeficiency virus (HIV) and herpesviruses, such as cytomegalovirus (CMV). GS 840 is a member of a new class of antiviral therapeutics known as nucleotide analogues, which have been shown to be potent inhibitors of viral replication with long durations of action and infrequent development of resistance.

"Adefovir dipivoxil appears to differ from other oral agents being developed for hepatitis B infection because it does not require processing by one of the host enzymes to become active," said Clinical Investigator Teresa L. Wright, M.D., Chief of Gastroenterology at the Veterans Administration Medical Center in San Francisco. "Adefovir dipivoxil may be an important option both for use as primary therapy and for use in combination with other hepatitis B drugs. Combination therapy may reduce the resistance to drugs seen in some patients with hepatitis B."

More than 1.5 million people in the United States and Europe, and more than 300 million people worldwide are chronically infected with hepatitis B virus. Long-term HBV infection can lead to severe complications, including cirrhosis, liver failure and liver cancer.

Current Phase II Studies - GS 840 for HBV

The two Phase II HBV studies are randomized, double-blind, placebo-controlled clinical trials evaluating oral GS 840 at one of three dose levels given once per day for 12 weeks. Both studies are designed to enroll patients in the United States, Canada, the United Kingdom and Australia. One study is designed to enroll 60 patients with normal liver enzyme levels, which is frequently observed in patients with long-term hepatitis B infection who contracted the virus at birth. The other study is designed to enroll 60 patients with elevated liver enzyme levels, which is frequently observed in people infected with HBV as adults. To determine the drug's safety and efficacy, researchers will compare changes in HBV viral load in blood and other markers of the disease among patients receiving different doses of GS 840 to those who receive placebo.

Prior Phase I/II Data - GS 840 for HBV

Previously, data from a Phase I/II human study demonstrated that treatment with GS 840 was well tolerated and provided significant and sustained antiviral activity against HBV. Patients who received GS 840 once daily for four weeks experienced a mean decline of 97 percent in viral load measured by HBV DNA in blood, compared to a seven percent viral load increase in patients who received placebo. All patients treated with GS 840 experienced a greater than 90 percent decrease in HBV DNA during dosing. These data were presented at the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 1996 and at the 47th Meeting of the American Association for the Study of Liver Diseases in November 1996.

Other Ongoing Studies - GS 840 for HIV Treatment and CMV Prevention

GS 840 also is in pivotal studies in combination with approved anti-HIV agents as multi-drug therapy for the potential treatment of HIV, the cause of AIDS. One Phase II/III study, which will enroll up to 400 people infected with HIV, will determine the safety and efficacy of GS 840 when administered in combination with antiretroviral therapies, including protease inhibitors currently approved for the treatment of patients infected with HIV.

In addition, The Terry Bein Community Programs for Clinical Research on AIDS (CPCRA), a National Institutes of Health sponsored organization, is conducting a Phase III study in up to 2,000 patients to determine GS 840's ability, when administered

with approved anti-retroviral therapies, to prolong survival and prevent CMV end-organ disease in patients with advanced AIDS.

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.