Gilead Sciences Announces Start of Expanded Access Program for PREVEON®

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An Investigational, Once-Daily Treatment for HIV Available to Patients with Limited Treatment Options

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Gilead Sciences, Inc. (NASDAQ:GILD) today announced an expanded access program for PREVEON; (adefovir dipivoxil) for people with advanced HIV infection in the United States who have limited treatment options. PREVEON, formerly referred to as adefovir dipivoxil or GS 840, is an investigational, orally-administered, once-daily, reverse transcriptase inhibitor currently being studied in a variety of late-stage clinical studies to treat human immunodeficiency virus (HIV) and prevent cytomegalovirus disease.

Gilead designed the expanded access program with input from HIV patient advocates and representatives of HIV/AIDS community organizations in the United States. Expanded access programs are part of an effort by the U.S. Food and Drug Administration (FDA) and the pharmaceutical industry to make investigational drugs available for the treatment of serious or life-threatening diseases in people with limited treatment options.

"Currently there is a great need for additional HIV treatments that are convenient to take and can be readily combined with other antiretroviral drugs," says James Rooney, M.D., Gilead's Vice President of Clinical Affairs. "In making PREVEON available through expanded access, patients with few alternatives will have another option to add to combination regimens."

Program Design - The program will make PREVEON available free of charge to HIV-positive patients at least 13 years of age who have failed treatment with at least two nucleoside analog reverse transcriptase inhibitors and one protease inhibitor, and who have had, within the past two months, a CD4 count less than or equal to 50 cells/mm3 and an HIV RNA level of greater than or equal to 30,000 copies/mL by PCR. Patients will receive PREVEON (120 mg tablet) and a nutritional supplement known as L-carnitine, once daily. Gilead will advise physicians to include, in addition to PREVEON, at least one new antiretroviral agent that has not been previously administered to the patients.

Physician Registration - A toll-free number (1-800-GILEAD-5 or 1-800-445-3235, press 1) has been established for physicians to call for more information regarding the Gilead expanded access program or to request registration materials. Kern-McNeill International (KMI) is the contract research organization that will administer the expanded access program.

Ongoing Clinical Program - PREVEON is currently being studied in late-stage clinical trials for the treatment of HIV in combination with other commercially available antiretroviral therapies, including protease inhibitors. Studies of PREVEON are currently enrolling patients at two dose levels (120 mg and 60 mg tablets) to examine the longer-term safety and efficacy of the drug in specific combinations and patient populations. During clinical trials, the most common side effects reported with PREVEON have been dose-related gastrointestinal effects, including nausea and loss of appetite. In addition, elevations in serum creatinine and liver transaminases have been reported. To date, more than 1,000 HIV-infected patients have been enrolled in clinical studies of PREVEON.

In addition to the expanded access program, the PREVEON studies currently enrolling patients include: a study in patients not previously treated with anti-HIV therapies (GS 411); a study in patients not previously treated with a protease inhibitor (GS 417); and studies sponsored by the National Institutes of Health's Adult AIDS Clinical Trials Group for patients who have failed triple combination regimens or treatment with protease inhibitors (ACTG 359 and ACTG 372). For more information on these ongoing clinical trials, contact Gilead's Medical Information Department at 1-800-GILEAD-5 (1-800-445-3235), press 3.

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 a pipeline of 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 and influenza virus. Gilead's research programs seek treatments for these and other viral infections, vascular diseases and cancer.