Gilead Broadens HIV Expanded Access Program for PREVEON®

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CD4 Count and HIV RNA Level Requirements Removed and Second Dose Level Added

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Gilead Sciences, Inc. (NASDAQ:GILD) announced today that it has broadened the entry criteria of its expanded access program for PREVEON (adefovir dipivoxil), for the treatment of human immunodeficiency virus (HIV) infection, to include patients in need of new therapeutic options regardless of CD4 cell count or HIV RNA level. The program makes PREVEON available free of charge to HIV infected adults in the United States who have failed treatment with at least two nucleoside analog reverse transcriptase inhibitors and one protease inhibitor. 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.

"Gilead worked closely with community advocates and the FDA to establish the expanded access program so that eligible patients may have access to PREVEON," said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead. "We have now broadened the program to provide access to PREVEON for less advanced patients who have failed their existing treatment regimens at higher CD4 levels."

The expanded access program for PREVEON, which began in December 1997, originally required that patients have HIV RNA greater than or equal to 30,000 copies/mL and a CD4 cell count less than or equal to 50 cells/mm3 to be eligible. The program no longer requires specific HIV RNA levels and CD4 counts in determining patient eligibility.

In addition to expanding the entry criteria, Gilead also modified the protocol to provide patients access to one of the two dose levels of PREVEON currently being studied in late stage clinical trials. Patients enrolled in the expanded access program may now be randomly assigned to receive either 120 mg or 60 mg once per day in combination with other antiretroviral agents. Alternatively, physicians may elect to provide patients with open-label PREVEON at the 120 mg dose.

PREVEON, given as one tablet once per day, is an investigational reverse transcriptase inhibitor in late stage clinical trials for the treatment of HIV. PREVEON is currently being tested in multiple studies at two dose levels (120 mg and 60 mg) in a variety of patient populations, including patients not previously treated with anti-HIV therapies (GS 411), those not previously treated with a protease inhibitor (GS 417) and those who have failed treatment with triple combination or protease inhibitor containing regimens (National Institutes of Health-sponsored studies ACTG 359 and ACTG 372). Two studies also are ongoing in patients with advanced HIV disease who have received prior treatment, one in the United States (CPCRA) and another in Europe and Australia (ADHOC).

To date, approximately 2,800 patients have been enrolled in PREVEON studies, including more than 1,000 in the expanded access program. During clinical testing, 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.

A toll-free number (1-800-GILEAD-5 or 1-800-445-3235, press 1) has been established for physicians and patients to call for more information regarding Gilead's expanded access program or to request registration materials. Kern McNeill International (KMI) is the clinical research organization facilitating the program. For information about Gilead's ongoing clinical trials, contact Gilead's Medical Information Department at 1-800-GILEAD-5, press 3.

Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops and commercializes proprietary therapeutics for important viral diseases, including a currently marketed product for the treatment of CMV retinitis, a sight-threatening viral infection in patients with AIDS. In addition, the Company is developing products to treat diseases caused by HIV, hepatitis B virus and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.