Gilead Sciences Announces Termination of Its U.S. Development Program for Adefovir Dipivoxil for HIV

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Gilead Sciences (Nasdaq: GILD) announced today the termination of its U.S. HIV development program for the investigational agent adefovir dipivoxil 60 mg. This decision follows a U.S. Food and Drug Administration (FDA) Advisory Committee meeting on November 1, 1999, at which the Committee recommended against accelerated approval of adefovir dipivoxil at this time for the treatment of HIV patients with disease progression.

In subsequent discussions with the FDA, Agency officials advised Gilead that additional results from controlled clinical trials would be required to further clarify the efficacy and safety of adefovir dipivoxil 60 mg. Additionally, the FDA indicated that it intended to issue a "not approvable letter" on the Company's new drug application (NDA) by the December 29, 1999 NDA action date, based on currently available data. As a result of these discussions, Gilead has determined that an additional investment of time and resources in this product is not appropriate given the other opportunities in Gilead's clinical pipeline.

"As indicated by the more than 9,000 patients with limited treatment options who have enrolled in the adefovir dipivoxil expanded access program over the past two years, we believe there is a significant need among patients for new treatment options – especially those that may offer antiviral activity against HIV strains that are resistant to commonly used medications," said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead Sciences. "Although we respect the suggestions of the Advisory Committee and the FDA for further clinical research, we believe it would be in the best interests of our shareholders and the HIV community if we allocate our resources to other development programs."

Gilead will focus its development efforts on its other late-stage clinical candidates. Tenofovir disoproxil fumarate (tenofovir DF) entered multinational Phase III clinical studies for the treatment of HIV infection earlier this week. Based on preclinical and preliminary clinical data, tenofovir DF appears to have a better profile than adefovir dipivoxil for HIV, in terms of both antiviral activity and safety. Additionally, the Company is developing adefovir dipivoxil for the treatment of hepatitis B virus infection (HBV). As compared to the HIV indication, adefovir dipivoxil for HBV is administered at lower doses (10 mg or 30 mg once per day) and has been shown to have potent antiviral activity. Adefovir dipivoxil for HBV is in long-term Phase III studies at multiple clinical sites in the United States, Europe and Asia.

Adefovir Dipivoxil for HIV - U.S. Clinical Trials and Expanded Access Program Status

Gilead has decided to halt new enrollment in its U.S. clinical trials and the expanded access program for adefovir dipivoxil for HIV. Patients now receiving adefovir dipivoxil in U.S. clinical trials will be given the opportunity to enroll in the expanded access program. Patients enrolled in the expanded access program will be able to continue to receive adefovir dipivoxil for as long as they and their treating physicians believe they are benefiting from the treatment. Because the average length of therapy on the expanded access program has been approximately nine months, the Company believes that its ongoing obligations under the program will be minimal by the end of 2000.

European Development

In September 1999, Gilead filed a Marketing Authorisation Application (MAA) for adefovir dipivoxil for HIV with the European Medicines Evaluation Agency (EMEA), under the centralized procedure for approval of human therapeutic products in all member states of the European Community. The Company anticipates receiving initial comments on the MAA from the EMEA during the first quarter of 2000. At that time, Gilead will evaluate the prospects for continued development of adefovir dipivoxil for HIV in Europe.

Gilead Sciences, headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA, Boulder, CO, San Dimas, CA, and Cambridge, UK, and sales and marketing organizations in the United States, Europe and Australia.