

Gilead Sciences Completes European Marketing Authorisation Application For Anti-HIV Agent Adefovir Dipivoxil 60 Mg

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Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Medicines Evaluation Agency (EMA) has accepted the Company's Marketing Authorisation Application (MAA) for adefovir dipivoxil 60 mg, an investigational, once-daily, oral nucleotide reverse transcriptase inhibitor intended for the treatment of patients with HIV infection. The application will be reviewed under the European Community centralized licensing procedure, which provides marketing authorization of human therapeutic products in all member states of the European Community. Review of the application will be coordinated by the EMA with regulatory authorities from Spain and the United Kingdom leading the process as rapporteur and co-rapporteur, respectively.

"The MAA submission for adefovir dipivoxil represents another important milestone toward our goal of providing new therapeutic options to patients with unmet medical needs in an accelerated manner," said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead Sciences. "Our recent acquisition of NeXstar Pharmaceuticals provides us with an international network of specialized sales professionals that, upon approval, will support the commercialization of this anti-HIV therapy in the European Union."

Gilead submitted a New Drug Application (NDA) for adefovir dipivoxil 60 mg for the potential treatment of HIV infection to the U.S. Food and Drug Administration (FDA) on June 29, 1999. Designated a "fast track" product by the FDA, adefovir dipivoxil is expected to undergo a six-month priority review. On September 21, 1999, Gilead submitted an additional NDA for an oral suspension formulation of adefovir dipivoxil, which was used in clinical studies of pediatric patients with HIV infection. The FDA Antiviral Drugs Advisory Committee is scheduled to review the adefovir dipivoxil NDA for the treatment of HIV infection on November 1, 1999.

Adefovir dipivoxil is dosed as a single daily 60 mg oral tablet taken with or without food. It is co-administered with 500 mg of the oral nutrient L-carnitine to replenish body carnitine levels that may be reduced by the administration of adefovir dipivoxil.

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.

This press release contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, concerning the timing and nature of potential registration filings for adefovir dipivoxil for HIV, regulatory review of these filings and presentation of clinical data at scientific conferences. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective as human therapeutics. Actual results could differ materially from those projected in this release. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 1998 on file with the U.S. Securities and Exchange Commission, copies of which are available from Gilead.