European Commission Approves Viread® for HIV-1 Infection in Children and Adolescents and for Chronic Hepatitis B in Adolescents

November 27, 2012 4:32 PM ET

-- New Oral Granule Formulation and Lower-Strength Tablets Available for New Indications --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 27, 2012-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted marketing authorization for two new indications for once-daily Viread® (tenofovir disoproxil fumarate). The first new indication permits the use of Viread in combination with other antiretroviral agents for the treatment of HIV-1 infected pediatric patients aged 2 to less than 18 years with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line pediatric agents. Additionally, Viread is now approved for the treatment of chronic hepatitis B virus (HBV) infection in adolescent patients aged 12 to less than 18 years with compensated liver disease and evidence of immune active disease. Today's authorization covers all 27 countries of the European Union (EU). Viread was approved for use in combination with other antiretroviral agents as a treatment for HIV-1 infection in adults and for chronic HBV in 2002 and 2008, respectively, and is the most-prescribed molecule for these diseases in major European countries.

Today's decision includes marketing authorization for a new oral granule formulation of Viread for HIV-1 infected children aged 2 to less than 6 years, and for HIV-1 infected children above 6 years of age for whom a solid dosage form is not appropriate. The agency also approved three new reduced-strength Viread tablets in doses of 123 mg, 163 mg and 204 mg for HIV-1 infected children aged 6 to less than 12 years. The use of the lower-strength tablets and the oral granule formulation are based on the patient's age and weight.

The existing, full-strength 245 mg Viread tablet formulation is now available for use by adolescents aged 12 to less than 18 years to treat both HIV-1 infection and chronic HBV infection in those with compensated liver disease. For adolescents and adults for whom the 245 mg tablets are not appropriate, the oral granule formulation may be used.

"We are pleased to provide new therapeutic options for younger patients living with HIV and chronic hepatitis B and will work to make these pediatric formulations available as quickly as possible," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences.

The new indications are supported by clinical data from three studies examining the use of Viread among children and adolescents with HIV and among adolescents with chronic HBV. The safety and efficacy of Viread has not been established in children less than 2 years of age for HIV treatment, or in children less than 12 years of age for the treatment of chronic HBV.

In an effort to accelerate the availability of pediatric formulations in low-income countries, where the majority of children with HIV live, Gilead has established incentives to encourage its Indian generic manufacturing partners to develop pediatric formulations of its HIV treatments. Through these partnerships, Gilead already makes Viread available at significantly reduced cost for adults living with HIV and chronic HBV in low-income countries.

EU Important Safety Product Information About Viread, Including Boxed Warnings

- Lactic acidosis, usually associated with hepatic steatosis, has been reported with the use of nucleoside analogues, including tenofovir disoproxil fumarate. Lactic acidosis has a high mortality and patients at increased risk should be followed closely.
- A multidisciplinary approach is recommended for the management of children and adolescents to weigh on a case-by-case basis the benefit-risk balance of treatment.
- Rare events of renal failure, renal impairment, elevated creatinine, hypophosphataemia and proximal tubulopathy (including Fanconi syndrome) have been reported with the use of tenofovir disoproxil fumarate.
- It is recommended that creatinine clearance is calculated in all adult patients prior to initiation therapy with Viread and renal function (creatinine clearance and serum phosphate) is also monitored every four weeks during the first year and the very three months. In patients at risk for renal impairment, more frequent monitoring should be considered. In children and adolescents, renal function (creatinine clearance and serum phosphate) should be evaluated prior to treatment and monitored during treatment as in adults.
- If renal abnormalities are detected or suspected in children and adolescents, consultation with a nephrologist should be obtained to consider interruption of Viread treatment.

- Use of Viread should be avoided with concurrent or recent use of nephrotoxic medications. If concomitant use of Viread and nephrotoxic agents is unavoidable, renal function must be monitored weekly.
- Dose interval adjustment is recommended in adult patients with moderate renal impairment (creatinine clearance 30-49 mL/min).
- Viread is not recommended in adult patients with severe renal impairment (creatinine clearance < 30 mL/min). If no alternative treatment is available, prolonged dose intervals may be used.
- Viread is not recommended for use in children and adolescents with renal impairment.
- Bone abnormalities (infrequently leading to fractures) may be associated with proximal renal tubulopathy and appropriate consultation should be obtained if suspected.
- Viread may cause a reduction in bone mineral density (BMD) and the effects of Viread associated changes in BMD on long term bone health and future fracture risk are currently unknown in children and adolescents. If bone abnormalities are detected or suspected in children and adolescents, consultation with an endocrinologist and /or nephrologist should be obtained.
- Immune reconstitution syndrome has been reported in patients treated with combination therapy, including Viread.
- Redistribution and/or accumulation of body fat have been observed in patients taking anti-HIV medicines. The cause and long-term effect of these conditions are unknown.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including the risk that healthcare providers may not see advantages of Viread for HIV-infected children and HBV-infected adolescents over other formulations and may therefore be reluctant to prescribe the product. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

EU Summary of Product Characteristics for Viread is available at http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp

Viread is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Patrick O'Brien, +1 650-522-1936 (Investors)
Stephen Head, +44 (208) 587-2359 (Media, Europe)
Cara Miller, +1 650-522-1616 (Media, U.S.)