European Commission Approves Gilead's Vitekta™, an Integrase Inhibitor for the Treatment of HIV-1 Infection

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Nov. 18, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted marketing authorization for Vitekta™ (elvitegravir 85 mg and 150 mg) tablets, an integrase inhibitor for the treatment of HIV-1 infection in adults without known mutations associated with resistance to elvitegravir. Vitekta is indicated for use as part of HIV treatment regimens that include a ritonavir-boosted protease inhibitor. Vitekta interferes with HIV replication by blocking the virus from integrating into the genetic material of human cells. In clinical trials, Vitekta was effective in suppressing HIV among patients with drug-resistant strains of HIV.

"Vitekta offers people with HIV who have failed prior therapy or who have developed drug resistance an important new treatment option," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Vitekta is only the second integrase inhibitor to become available in the European Union. Today's approval exemplifies Gilead's ongoing commitment to meeting the evolving needs of people living with HIV."

Vitekta has been approved in two doses: an 85 mg tablet is indicated for use with the ritonavir-boosted protease inhibitors atazanavir 300 mg and lopinavir 400 mg; and a 150 mg tablet is indicated for use with the ritonavir-boosted protease inhibitors darunavir 600 mg and fosamprenavir 700 mg. The approval is supported by 96-week data from a Phase 3 study (Study 145) in which Vitekta dosed once daily was found to be non-inferior to the integrase inhibitor raltegravir dosed twice daily, each administered with a background regimen that included a fully active ritonavir-boosted protease inhibitor and a second antiretroviral agent. Patients enrolled in the trial were required to have genotypic HIV drug resistance or at least six months of treatment experience with two or more different classes of antiretrovirals.

Vitekta was well tolerated in clinical studies and most adverse reactions were mild to moderate. The most common adverse reactions (all grades) observed were diarrhea (7.1 percent) and nausea (4 percent); please see additional Important Safety Information below.

Vitekta is also a component of Gilead's Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), a once-daily single tablet regimen for HIV that was approved in the United States in August 2012 for treatment-naïve adults and by the European Commission in May 2013 for adults who are treatment-naïve or who have no known mutations associated with resistance to any of the three antiretroviral agents in Stribild. Gilead submitted a new drug application to the U.S. Food and Drug Administration (FDA) for Vitekta as a single agent in June 2012 and received a Complete Response Letter in April 2013. Gilead is working on resubmitting the application to the FDA.

About Vitekta

Vitekta was licensed by Gilead from Japan Tobacco Inc. (JT) in March 2005. Under the terms of Gilead's agreement with JT, Gilead has exclusive rights to develop and commercialize Vitekta as a single agent in all countries of the world, excluding Japan, where JT retains rights.

Indication and Important Safety Information about Vitekta

Vitekta co-administered with a ritonavir-boosted protease inhibitor and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults who are infected with HIV-1 without known mutations associated with resistance to elvitegravir.

Elvitegravir-resistant viruses show cross-resistance to the integrase strand transfer inhibitor raltegravir in most cases. Elvitegravir has a relatively low genetic barrier to resistance. Therefore, whenever possible, Vitekta should be administered with a fully active ritonavir-boosted protease inhibitor and a second fully active antiretroviral agent to minimise the potential for virologic failure and the development of resistance.

Elvitegravir is primarily metabolised by CYP3A. Co-administration of Vitekta with strong CYP3A inducers (including St. John's wort [Hypericum perforatum], rifampicin, carbamazepine, phenobarbital and phenytoin) is contraindicated. Co-administration of Vitekta with moderate CYP3A inducers (including, but not limited to, efavirenz and bosentan) is not recommended.

Due to the need for co-administration of Vitekta with a ritonavir-boosted protease inhibitor, prescribers should consult the Summary of Product Characteristics of the co-administered protease inhibitor and ritonavir for a description of contraindicated medicinal products and other significant drug-drug interactions that may cause potentially life-threatening adverse reactions or loss of therapeutic effect and possible development of resistance.

Atazanavir/ritonavir and lopinavir/ritonavir have been shown to significantly increase the plasma concentrations of elvitegravir. When used in combination with atazanavir/ritonavir and lopinavir/ritonavir, the dose of Vitekta should be decreased from 150 mg once daily to 85 mg once daily. Vitekta must be used in combination with a ritonavir-boosted protease inhibitor. Vitekta should not be used with a protease inhibitor boosted by another agent as dosing recommendations for such combinations have not been established. Boosting elvitegravir with an agent other than ritonavir may result in suboptimal plasma concentrations of elvitegravir and/or the protease inhibitor leading to loss of therapeutic effect and possible development of resistance.

Vitekta should not be used in combination with products containing elvitegravir or pharmacokinetic boosting agents other than ritonavir.

Female patients of childbearing potential should use either a hormonal contraceptive containing at least 30 µg ethinylestradiol and containing norgestimate as the progestagen or should use an alternative reliable method of contraception. Co-administration of elvitegravir with oral contraceptives containing progestagens other than norgestimate have not been studied and, therefore, should be avoided. Patients using oestrogens as hormone replacement therapy should be clinically monitored for signs of oestrogen deficiency.

Elvitegravir has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). No dose adjustment of Vitekta is required in patients with mild (Child-Pugh Class A) or moderate hepatic impairment (Child-Pugh Class B).

Immune Reactivation Syndrome has been reported in patients treated with combination therapy.

Vitekta contains lactose. Consequently, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product.

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 and South 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 physicians may not see advantages of Vitekta over other HIV therapies and may therefore be reluctant to prescribe the product. In addition, pending marketing applications for Vitekta in the United States and other regions may not be approved or approval may be delayed, and marketing approvals, if granted, may have significant limitations on their use. 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, 2013, 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 Vitekta and Stribild are available at http://www.ema.europa.eu/ema/

U.S. full prescribing information for Stribild, including BOXED WARNING, is available at www.gilead.com.

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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.

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