FOR IMMEDIATE RELEASE

News

Abbott Receives European Approval for Once-Daily Dosing of Kaletra® (lopinavir/ritonavir) Tablet

New Approval Expands Dosing Options for Adult HIV-Infected Patients New to Antiretroviral Therapy

Abbott Park, Illinois, September 14, 2009 – Abbott announced today that it has received marketing authorization from the European Commission for once-daily dosing of the Kaletra® (lopinavir/ritonavir) tablet, the company’s leading HIV protease inhibitor (PI), in adult patients new to HIV therapy. The Kaletra tablet is now approved for once-daily as well as twice-daily use in this patient population in combination with other antiretroviral agents, giving physicians another option when deciding on the most appropriate HIV dosing regimen.

"The approval of this new dosing option for Kaletra in Europe is valuable for adult patients who may benefit from being able to take their prescribed Kaletra regimen one time each day," said Scott Brun, M.D., divisional vice president, Infectious Disease Development, Global Pharmaceutical Research and Development, Abbott. "Once-daily dosing of a co-formulated tablet, such as Kaletra, is especially important for patients whose life circumstances present challenges to treatment compliance."

The new dosing indication is available in cases where once-daily Kaletra administration is considered necessary for the management of the patient. Kaletra dosed once-daily might be associated with a lesser sustainability of virologic suppression and a higher risk of diarrhea compared to the recommended standard twice-daily dosage. Kaletra once-daily dosing is not validated in antiretroviral experienced patients and has not been evaluated in pediatric patients. Kaletra must not be administered once daily in combination with efavirenz, nevirapine, nelfinavir, amprenavir, carbamazepine, phenobarbital or phenytoin.

The Kaletra tablet can be taken with or without food and does not require refrigeration – two important advances in delivering HIV medicine.

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"With the management of HIV, it is important to consider the needs of each patient," said Juan González-García, M.D., Hospital Universitario La Paz, Madrid, Spain. "New treatment options, such as once-daily dosing of Kaletra, have increased the interest of physicians and patients in identifying treatments that can be tailored to a patient’s lifestyle rather than a patient adapting his or her lifestyle to the treatment."

About Kaletra

Kaletra is an inhibitor of human immunodeficiency virus (HIV) protease enzyme used for the treatment of HIV-1 infected adults and children above the age of two years. Kaletra is used in combination with other antiretroviral medicines.

Kaletra does not cure HIV infection or AIDS and does not reduce the risk of passing HIV to others.

Important Safety Information

Kaletra should not be taken by patients who have had an allergic reaction to any of its ingredients, including lopinavir or ritonavir, or any of the excipients, or by patients with severe liver problems.

Do not take Kaletra with any of the following medicines: astemizole, terfenadine, oral midazolam, triazolam, pimozide, cisapride, ergotamine, dihydroergotamine, ergonovine, and methylergonovine, amiodarone, vardenafil and products containing St. John’s Wort (Hypericum perforatum).

Patients taking certain medicines with Kaletra may result in increased levels in the body of these other medicines and could increase or prolong their effect and/or adverse reactions. Patients must tell their doctor about all the medicines, including those medicines they can buy without a prescription, they are taking or are planning to take before taking Kaletra. This is because taking Kaletra with some medicines can result in serious or life threatening problems.

Kaletra must not be taken once-daily in combination with efavirenz, nevirapine, nelfinavir, amprenavir, carbamazepine, phenobarbital, or phenytoin.
Patients should speak to their doctor if they have a history of liver disease. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for control of liver function.

Treatment with Kaletra has resulted in increases, sometimes marked, in the concentration of total triglycerides and cholesterol.

Cases of pancreatitis have been reported in patients taking Kaletra. Patients should contact their doctor if they have nausea, vomiting or abdominal pain, which may be signs of pancreatitis.

In patients taking protease inhibitors, increased bleeding (in patients with hemophilia type A and B) and new onset diabetes mellitus, hyperglycaemia or exacerbation of existing diabetes mellitus has been reported.

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. The long-term consequences of these events are currently unknown.

In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. Symptoms of infection should be reported to a doctor immediately.

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis. Signs are joint stiffness, aches and pains (especially in the hip, knee and shoulder) and difficulty in movement. These symptoms require that patients contact their doctor.
Kaletra has been shown to cause modest asymptomatic prolongation of the PR interval in some healthy adult subjects. Rare reports of second or third degree atrioventricular block in patients with underlying structural heart disease and pre-existing conduction system abnormalities or in patients receiving drugs known to prolong the PR interval (such as verapamil or atazanavir) have been reported in patients receiving Kaletra. Kaletra should be used with caution in such patients.

Patients taking oral contraceptive or using a patch to prevent pregnancy should use an additional or different type of contraception since Kaletra may reduce the effectiveness of oral and patch contraceptives.

Pregnant or nursing mothers should not take Kaletra unless specifically directed by their doctor.

Kaletra should not be given to children younger than two years of age unless specifically directed by their doctor. Kaletra once-daily has not been evaluated in pediatric patients.

In Kaletra adult clinical trials, the very common and commonly reported side effects of moderate to severe intensity were diarrhea, insomnia, headache, burning or prickling sensation around the mouth and extremities, nausea, vomiting, abdominal pain, abnormal stools, dyspepsia, flatulence, gastrointestinal disorder, rash, lipodystrophy, acne, and weakness. This is not a complete list of reported side effects.

For more information about Kaletra, local Summary of Product Characteristics should be consulted.

Abbott and HIV/AIDS
Abbott has been a leader in HIV/AIDS research since the early years of the epidemic. In 1985, the company developed the first licensed test to detect HIV antibodies in the blood and remains a leader in HIV diagnostics. Abbott retroviral and hepatitis tests are used to screen more than half of the world’s donated blood supply. Abbott has developed two protease inhibitors for the treatment of HIV.
About Abbott
Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries.

Abbott’s news releases and other information are available on the company’s Web site at www.abbott.com.

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