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News

Abbott Submits E.U. and U.S. Regulatory Filings for New Lower-Strength Kaletra[®] and Aluvia[®] (lopinavir/ritonavir) Tablet Suitable for Pediatric Use

ABBOTT PARK, Ill., July 19, 2007 – Abbott has applied to the European Medicines Agency (EMA) and to the U.S. Food and Drug Administration (FDA) for approval of a new, lower-strength tablet of its leading HIV protease inhibitor, known as Kaletra[®] and Aluvia[®] (lopinavir/ritonavir). Abbott's lopinavir/ritonavir tablet is the first and only co-formulated protease inhibitor tablet that can be used in children.

The new tablet formulation will complement the availability of Kaletra oral solution, which has been available since September 2000. The new tablet formulation does not require refrigeration and can be taken with or without a meal.

All lopinavir/ritonavir formulations are among the lowest priced protease inhibitors in the developing world. In all countries where the lower-strength Kaletra tablet will be available, the price of lower-strength tablet will be half the cost of the full-strength tablet.

According to the World Health Organization (WHO), 2.3 million children under the age of 15 are living with HIV/AIDS worldwide; 1,400 children die from AIDS-related illnesses each day; and an additional 1,800 children are infected with HIV daily. The WHO recommends lopinavir/ritonavir for the treatment of children who no longer respond to first-line HIV medicines. The U.S. Department of Health and Human Services recommends lopinavir/ritonavir for the initial treatment of children with HIV.

"Antiviral medicines can make a significant difference especially for a child," said Pamela W. Barnes, president and CEO of the Elizabeth Glaser Pediatric AIDS Foundation. "When children have HIV treatment made in a dose and form they are able to take, we can give health care providers medicines to help treat these children and manage their disease."

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Given the needs in the developing world, Abbott intends to make the new lower-strength tablet available globally as broadly as the already-approved tablet, which at 150 countries will be the most broadly registered HIV medicine in developing countries. Abbott is working to ensure availability for the developing world as quickly as possible. An important first step occurred when Abbott received accelerated review by the EMEA and a priority review by the FDA. The regulatory review process in the developing world requires EMEA approval first to obtain a Certificate of Pharmaceutical Product (CPP), which must be included with the regulatory filing documents at the time of submission. As a result, Abbott is working with global regulatory agencies on a country-by-country basis to negotiate early regulatory submissions (before the CPP is available) with local governments. Abbott is and will continue to explore all locally acceptable regulatory opportunities to help make the product available to patients as soon as possible.

"There are more than 2 million HIV-infected children across the world and the majority live in resource-limited settings where access to a refrigerator and regular meals are not a guarantee," said Prof. Diana Gibb, M.D., department of infectious diseases, Great Ormond Street Hospital for Children, London, U.K. "The development and approval of a lower-strength lopinavir/ritonavir tablet will add to the value of this product for treating children living with HIV."

The lower-strength tablet contains 100 mg of lopinavir and 25 mg of ritonavir compared with the current tablet strength of 200 mg of lopinavir and 50 mg of ritonavir.

Pediatric dosing of Kaletra is based on body surface area or weight. When approved, the new, lower-strength tablet will offer more dosing flexibility for suitable pediatric patients than the currently approved full-strength tablet. The oral solution of lopinavir/ritonavir continues to be available for patients around the world, though it must be taken with food and also requires refrigeration.

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"The new, lower-strength tablet formulation of lopinavir/ritonavir is a significant innovation in the care for people living with HIV," said Scott C. Brun, M.D., divisional vice president, infectious disease/renal development, Global Pharmaceutical Research and Development, Abbott. "It is part of Abbott's continued commitment to develop the most novel formulation options for HIV patients around the world, especially in developing nations where the burden is greatest."

Indication and Important Safety Information for Lopinavir/ritonavir

Indication

Kaletra is indicated for the treatment of HIV-1 infected adults and children above the age of two years. It is used in combination with other antiretroviral agents.

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

Kaletra Important Safety Information

Globally, prescribing information varies; refer to the individual country product label for complete information. For U.S. safety information visit www.KALETRA.com.

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.

Taking certain medications with Kaletra could cause serious side effects that could be life threatening. Do not take Kaletra with astemizole, terfenadine, midazolam, triazolam, pimozide, cisapride, ergotamine, dihydroergotamine, ergonovine, and methylegonovine, rifampicin, amiodarone, vardenafil and products containing St. John's Wort (*Hypericum perforatum*).

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Medical advice and approval must be sought before Kaletra is taken with lovastatin, simvastatin, some medicines affecting the immune system (e.g., cyclosporin, sirolimus (rapamycin), tacrolimus), various steroids (e.g., dexamethasone, fluticasone propionate, ethinyl oestradiol), other protease inhibitors, certain heart medicines such as calcium channel antagonists, (e.g., felodipine, nifedipine, nicardipine) and medicines used to correct heart rhythm (e.g., bepridil, systemic lidocaine, quinidine), antifungals, (e.g., ketoconazole, itraconazole), morphine-like medicines (e.g., methadone) anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital), warfarin, certain antibiotics (i.e., rifabutin, clarithromycin), certain antidepressants (i.e., trazodone) and voriconazole.

Kaletra may interact with erectile dysfunction agents (e.g., sildenafil or tadalafil). Lower doses of these medicines should be prescribed in patients taking Kaletra.

Kaletra may interact with digoxin (heart medicine); monitoring by a physician is recommended.

Taking Kaletra with certain medicines can cause increased levels of these other medicines in the body. This could increase or prolong their effects and/or adverse reactions, which may result in serious or life-threatening problems. Because of this, patients must tell their doctor about all medicines they are taking or planning to take, including those medicines that can be bought without a prescription and herbal preparations.

Patients using an oral contraceptive or using a patch contraceptive to prevent pregnancy should use an additional or alternative type of contraception since Kaletra may reduce the effectiveness of these products.

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

Kaletra oral solution contains 42 percent alcohol. While taking Kaletra oral solution, patients should not take any medicines that may cause a reaction with alcohol such as disulfiram.

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It is important that Kaletra oral solution is taken with food. Kaletra tablets may be taken with or without food.

Cases of pancreatitis have been reported in patients taking Kaletra. Liver problems, which can be fatal, have also been reported. Patients should tell their doctor if they have had liver disease such as chronic hepatitis B or C as they are at increased risk for severe and potentially fatal liver adverse events. These patients may require blood tests for control of liver function.

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Patients should contact their doctor if they notice changes in body fat.

In patients taking protease inhibitors, increased bleeding (in patients with hemophilia type A and B) has been reported.

Combination antiretroviral therapy may cause new cases of diabetes and high blood sugar or worsening of existing diabetes, as well as increased fats and raised lactic acid in the blood. The long-term risks for complications due to increases in triglycerides and cholesterol are not known at this time. In addition, large amounts of triglycerides have been considered a risk factor for pancreatitis.

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 and symptoms 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.

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In lopinavir/ritonavir adult clinical trials, the very common and commonly reported side effects of moderate to severe intensity were diarrhea, insomnia, headache, nausea, vomiting, abdominal pain, abnormal stools, dyspepsia, flatulence, gastrointestinal disorder, rash, lipodystrophy, weakness, and abnormal liver enzymes. This is not a complete list of reported side effects.

In children two years of age and older, the safety profile is similar to that seen in adults.

For more information about Kaletra, please consult your local prescribing information.

Storage Conditions

Kaletra tablets do not require any special storage conditions.

Kaletra oral solution: Store in a refrigerator (2°-8° C). If kept outside of the refrigerator, do not store above 25° C and discard any unused contents after 42 days (6 weeks). Avoid exposure to excessive heat.

About Abbott

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.

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 65,000 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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