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News

Abbott Agrees with WHO Director-General to Expand Access to Kaletra/Aluvia (lopinavir/ritonavir)

Abbott Reduces Price of Kaletra/Aluvia in Low and Low-Middle Income Countries to \$1,000

ABBOTT PARK, Ill., April 10, 2007 — Abbott and WHO Director-General, Margaret Chan, have agreed on a balanced approach to provide Kaletra/Aluvia (lopinavir/ritonavir) capsules and tablets to more patients in the developing world, while supporting continued long-term biopharmaceutical research and development. In the interest of international public health, Director-General Chan approached Abbott to discuss how to improve affordability and access while maintaining incentives to support developing new medicines.

To meet the needs of countries committed to expanding HIV/AIDS treatment, Abbott will offer the governments of more than 40 low and low-middle income countries (as defined by World Bank criteria) and NGOs a new price of \$1,000 per patient per year. This price is lower than any generic price available in the world today for this medicine and is approximately 55 percent less than the average current price for these countries.

Abbott will immediately begin discussions with individual countries where Abbott's patents are respected to maximize the number of patients that can be provided Kaletra/Aluvia capsules and tablets at this new price.

Abbott is taking this action in order to further increase access and address the debate around pricing of HIV medicines: by increasing affordability while preserving the system that enables the discovery of new medicines. The patents of scientists and inventors must exist so that there are incentives for sustained research and development. Without this system, the miracle drugs the world enjoys today, including HIV medicines, would not exist.

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Media:
Melissa Brotz
(847) 935-3456: Office
(847) 772-2761: Mobile

Jennifer Smoter
(847) 935-8865: Office
(847) 772-4631: Mobile

Financial Community:
Larry Peepo
(847) 935-6722

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Specifically, with regard to Thailand, Abbott appreciates and fully respects the suggestion of Director-General Chan that more work needs to be done with the government of Thailand to achieve a positive outcome. Meanwhile, Kaletra capsules remain available in Thailand and will be eligible for the new price.

Today, Kaletra capsules are registered in 118 countries, making it the most widely registered HIV medicine. Kaletra/Aluvia tablets will be registered in more than 150 countries at the completion of the registration process.

About Kaletra/Aluvia

Kaletra (lopinavir/ritonavir) is indicated for the treatment of HIV-1 infected adults and children above the age of 2 years, in combination with other antiretroviral agents. Most experience with Kaletra is derived from the use of the product in antiretroviral therapy naïve patients. Data in heavily pretreated protease inhibitor experienced patients are limited. There are limited data on salvage therapy on patients who have failed therapy with Kaletra.

The choice of Kaletra to treat protease inhibitor experienced HIV-1 infected patients should be based on individual viral resistance testing and treatment history of patients. Kaletra is not recommended for use in children below 2 years of age due to insufficient data on safety and efficacy.

Important Safety Information

Kaletra should not be given to patients who have had an allergic reaction to the active substances or any of the excipients, or by patients with severe hepatic insufficiency.

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Kaletra is contraindicated with astemizole, terfenadine, midazolam, triazolam, cisapride, pimozide, amiodarone, ergot alkaloids (e.g., ergotamine, dihydroergotamine, ergonovine and methylergonovine), products containing St. John's wort (*Hypericum perforatum*) and vardenafil. Kaletra should not be co-administered with lovastatin, simvastatin, rifampicin, fluticasone or other glucocorticoids.

Co-administration of efavirenz, nevirapine, nelfinavir or amprenavir with Kaletra tablets 400/100 mg is not recommended. If co-administration of these products with Kaletra is clinically indicated, a dose increase of Kaletra tablets to 600/150 mg twice daily may be considered. However, as the safety of high doses of Kaletra has not been established, safety should be closely monitored when Kaletra tablets 600/150 mg twice daily is administered.

Particular caution must be used when prescribing sildenafil or tadalafil in patients receiving Kaletra. Concomitant use of Kaletra with tadalafil or sildenafil is expected to substantially increase PDE5 inhibitor associated adverse reactions including hypotension, syncope, visual changes and prolonged erection.

Particular caution must be used when prescribing Kaletra and medicinal products known to induce QT interval prolongation such as chlorpheniramine, quinidine, erythromycin, or clarithromycin.

Levels of ethinyl estradiol may decrease when estrogen-based oral contraceptives are co-administered with Kaletra; alternative or additional contraceptive measures are to be used.

Please consult your local prescribing information for any additional country specific prescribing recommendations.

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Cases of pancreatitis have been reported in patients receiving Kaletra, including those who developed hypertriglyceridemia.

Kaletra is contraindicated in patients with severe liver impairment. Patients with chronic hepatitis B or C and treated with combination antiretroviral therapy are at an increased risk for severe and potentially fatal hepatic adverse events. Patients should be monitored, and if there is evidence of worsening liver disease in such patients, interruption or discontinuation of treatment should be considered.

In patients receiving protease inhibitors, increased bleeding (in patients with hemophilia), new onset or exacerbation of diabetes mellitus and hyperglycemia have been reported.

Combination antiretroviral therapy has been associated with redistribution of body fat (lipodystrophy) in HIV patients. The long-term consequences of these events are currently unknown.

Treatment with Kaletra has resulted in increases, sometimes marked, in total cholesterol and triglycerides, which should be monitored before and during therapy. Immune reactivation syndrome has been reported in HIV-infected patients with severe immune deficiency at the time of institution of combination antiretroviral therapy. Although the etiology is considered multifactorial (including corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index), cases of osteonecrosis have been reported particularly in patients with advanced HIV-disease and/or long-term exposure to combination antiretroviral therapy.

At this stage of development, little information is available on the cross-resistance of viruses selected during therapy with Kaletra.

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In Kaletra clinical trials, adverse reactions of moderate to severe intensity with possible or probable relationship to Kaletra were diarrhea, nausea, vomiting, abdominal pain, abnormal stools, dyspepsia, flatulence, gastrointestinal disorder, insomnia, headache, rash, lipodystrophy, and asthenia. In children 2 years of age and older, the nature of the safety profile is similar to that seen in adults.

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 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.abott.com.

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