



News

For Immediate Release

Canadian Media
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**ABBOTT'S NEW TABLET FORMULATION OF KALETRA[®]
(LOPINAVIR/RITONAVIR) APPROVED IN CANADA**

*– New Formulation of the Leading Protease Inhibitor
Reduces Pill Count, Does Not Require Refrigeration –*

Montréal, September 12, 2006 – Abbott Canada announced today that it has received marketing authorization from Health Canada for the tablet formulation of Kaletra[®] (lopinavir/ritonavir), a new, more convenient version of the leading protease inhibitor (PI) prescribed worldwide for the treatment of HIV. The Kaletra tablet allows adult patients to take fewer pills with or without food as part of their treatment regimen while providing drug levels in the blood similar to that of the capsule formulation. In addition, the tablet formulation does not require refrigeration.

Kaletra is the number one prescribed PI for the treatment of HIV worldwide and has been taken by hundreds of thousands of patients since the drug was introduced in 2000. According to the updated guidelines released by a panel convened by the U.S. Department of Health and Human Services in October 2005, Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents, "Kaletra, in combination with zidovudine and lamivudine or emtricitabine, are recommended as the preferred PI-based regimens for the treatment of patients new to HIV therapy."

"Kaletra is a proven HIV treatment for both ARV naive and experienced patients. This new and more convenient tablet formulation will be preferred by both physicians and patients," said Sharon Walmsley, MD FRCPC, Associate Professor of Medicine, University of Toronto.

The approved tablet formulation of Kaletra is designed to offer patients new benefits not available with the current soft capsules, enhancing dosing convenience without compromising efficacy. Specifically, this new formulation offers:

- Reduced pill count – though the total daily dose of Kaletra in adults (800 mg lopinavir/200 mg ritonavir) is unchanged, patients will now only need to take **four** tablets per day, as opposed to six capsules;
- Dosing with or without food, providing patients greater flexibility – the current soft capsule formulation should be taken with food; and
- No refrigeration required – unlike the current soft capsule formulation, which requires refrigeration, the new Kaletra tablet can be stored at room temperature.

Kaletra was developed using Abbott's proprietary Meltrex™ melt-extrusion technology, which enables a stable, solid distribution of the active pharmaceutical ingredients within a tablet that provides similar drug levels in the blood relative to the capsules. A single Kaletra tablet will now be composed of 200 mg lopinavir and 50 mg ritonavir, as compared to 133.3 mg lopinavir and 33.3 mg ritonavir in the previously introduced soft capsule.

"The tablet formulation of Kaletra is another example of Abbott's continued commitment to offering the next step in simple, safe and effective treatments for the HIV community," said Scott Brun, M.D., divisional vice president, Infectious Disease Development, Abbott.

Kaletra Tablet Availability

With approval of the more convenient Kaletra tablets in Canada, it is expected that the majority of patients will convert to the tablet formulation. Patients should finish taking their current supply of Kaletra capsules before starting a new Kaletra tablet prescription. Patients must **never** take Kaletra tablets and capsules together; they should carefully follow their doctor's directions, and take their medication exactly as written on the label. Capsules will remain available for now.

To assist with the conversion from Kaletra capsules to Kaletra tablets, Abbott is providing educational information to health care providers and the HIV community.

Kaletra Safety Information

Kaletra is always used in combination with other anti-HIV medicines to treat people with HIV infection. Kaletra should not be taken by patients who have had an allergic reaction to lopinavir/ritonavir or any of its ingredients, including lopinavir or ritonavir.

Taking certain medications with Kaletra could create the potential for serious side effects that could be life threatening. Kaletra should not be taken with astemizole, cisapride, dihydroergotamine, ergonovine, ergotamine, methylergonovine, midazolam, pimozide, terfenadine or triazolam.

In addition, Kaletra should not be taken with lovastatin, rifampin, simvastatin, vardenafil, or products containing St. John's Wort (*Hypericum perforatum*). Particular caution should be used when taking Kaletra with sildenafil or tadalafil. Kaletra may also interact with certain other medications; consequently, patients should discuss all medicines, including those without a prescription and herbal preparations they are taking or plan to take, with their doctor or pharmacist.

Pancreatitis and liver problems, which can be fatal, have been reported. Patients should tell their doctor if they have had liver disease such as hepatitis. In patients taking protease inhibitors, increased bleeding (in patients with hemophilia) and diabetes/high blood sugar have occurred. Changes in body fat have been seen in some patients receiving antiretroviral therapy. Some patients receiving Kaletra have had large increases in triglycerides and cholesterol. Varying degrees of cross-resistance among protease inhibitors have been observed.

In Kaletra clinical trials, the most commonly reported side effects of moderate-to-severe intensity were abdominal pain, abnormal bowel movements, diarrhea, feeling weak or tired, headache, nausea and vomiting. Children taking Kaletra may sometimes get a skin rash. This is not a complete list of reported side effects. Kaletra oral solution contains alcohol.

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

For more information about Kaletra including prescribing information visit www.abbott.ca.

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. With Kaletra, Abbott has developed two protease inhibitors, and offers nutritional products that meet the unique dietary needs of hundreds of thousands of people living with HIV.

Abbott and the Abbott Fund also are investing \$100 million in developing countries to advance HIV testing, treatment and support services for people affected by HIV/AIDS. Through pioneering programs that help prevent

mother-to-child transmission of HIV, expand access to testing and treatment, strengthen health systems, and provide support for children, Abbott has helped improve the health and lives of millions of people affected by HIV/AIDS.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, device and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

Abbott Canada is headquartered in Saint-Laurent, Québec, and employs approximately 1,200 people.

Abbott Canada's news releases and other information are available on the company's Web site at www.abbott.ca.

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