



News

Abbott Prepares to Submit Heat-Stable Norvir® Tablet for Registration by End of Year

Tablet Formulation Expected to Increase Convenience and Delivers on Commitment to HIV Patients

ABBOTT PARK, Ill., July 29, 2008 – Abbott has announced it will submit registration applications for a novel tablet formulation of its protease inhibitor (PI) Norvir® (ritonavir) and request priority review by U.S. and E.U. authorities before the end of the year. This new, heat-stable formulation will not require refrigeration, which will make it more convenient, particularly in developing countries where the majority of people with HIV live.

Abbott will present data from a pivotal study of bioavailability, which compares the heat-stable tablet formulation to the current soft gel capsule, at the XVII International AIDS Conference in Mexico City (AIDS 2008) on Aug. 7, 2008.

First approved in 1996, ritonavir remains one of the most commonly prescribed medicines as part of combination therapy for HIV. Realizing the value of Norvir in the current therapeutic environment has enabled Abbott to invest in the development of this new formulation, which will better respond to the needs of doctors and patients. In the past four-and-a-half years, Abbott has invested more than US\$350 million into further development of Kaletra® and Norvir, including creating a new tablet version of Kaletra and Norvir, introducing a lower-strength formulation of Kaletra, and building manufacturing capacity for its new formulations.

"The heat-stable ritonavir formulation represents a significant advancement for patients who need this medicine," said Sharon Walmsley, M.D., professor of medicine, University of Toronto. "Abbott scientists overcame complex formulation challenges to develop a more convenient treatment."

The Norvir tablet was developed using the Meltrex® technology, which was also used in the development of Abbott's Kaletra (lopinavir/ritonavir) tablets, a combination of ritonavir and lopinavir. However, ritonavir on its own required a different formulation to ensure the tablets remain stable over time and that the body can absorb the drug. Abbott scientists evaluated a number of candidate formulations, before developing the final formulation, to meet these objectives.

Ultimately, if approved, Abbott intends to register the new Norvir tablet as broadly worldwide as lopinavir/ritonavir, the most widely registered PI worldwide, according to the World Health Organization. The lopinavir/ritonavir tablet is approved for sale, available (in countries where no regulatory approval is needed), or has been submitted for registration in 157 countries around the world.

About Abbott's Commitment to Fighting HIV/AIDS

HIV/AIDS is a global problem that demands shared commitment and shared responsibility. Abbott is committed to working with governments, multilateral organizations, nongovernmental organizations and patient groups to expand access to HIV treatment around the world.

Abbott's lopinavir/ritonavir formulations are among the lowest-priced protease inhibitors in the developing world. Abbott has been providing its HIV medicines at a price of US\$500 per adult patient per year in all African and least developed countries since 2002, making these medicines more affordable than any generic copies.

Abbott and the company's philanthropic foundation, Abbott Fund, have invested more than US\$100 million in the fight against HIV/AIDS in Africa and the developing world. Abbott Fund-supported programs have served more than 700,000 children and families. In addition, more than 250,000 patients have been tested through Abbott Fund-supported voluntary counseling and testing programs, with thousands being referred to treatment programs. Abbott also has donated more than nine million rapid HIV tests to help prevent mother-to-child HIV transmission.

In addition to Abbott's programs to expand access for people living with HIV, the Abbott Fund, the philanthropic arm of Abbott, has invested more than \$125 million to fight AIDS in the developing world since 2000. In 2008, Abbott Fund will provide grants totaling more than \$12 million to support children and families impacted by AIDS.

For more information about Abbott's commitment to fighting HIV/AIDS, please visit www.abbott.com/hiv.

Globally, prescribing information varies; refer to the individual country full prescribing information for complete information. For Canadian Full Prescribing Information about Norvir and Kaletra, including Important Safety Information, please visit www.abbott.ca.

**About Norvir
Indication**

NORVIR (ritonavir) is a class of medicines called HIV protease (PRO-tee-ase) inhibitors. NORVIR is used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection. NORVIR is for adults and for children age one month and older.

Refrigeration of NORVIR soft gelatin capsules by the patient is recommended, but not required if used within 30 days and stored below 77°F (25°C), Avoid exposing NORVIR soft gelatin capsules to excessive heat or cold. Store in the original container.

Store NORVIR oral solution at room temperature. Do not refrigerate NORVIR oral solution. Avoid exposing NORVIR oral solution to excessive heat or cold. Store in the original container.

About Kaletra

Indication

KALETRA (lopinavir/ritonavir) is a human immunodeficiency virus-1 (HIV-1) protease inhibitor. KALETRA is always used in combination with other anti-HIV-1 medicines for the treatment of HIV-1 infection. KALETRA is a combination of two medicines, lopinavir and ritonavir. KALETRA is for adults and for children age six months and older.

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All strengths of KALETRA tablets should be swallowed whole and not chewed, broken, or crushed.

KALETRA tablets should be stored at room temperature. Exposure of this product to high humidity outside the pharmacy container for longer than two weeks is not recommended.

Refrigerated KALETRA oral solution remains stable until the expiration date printed on the label. If stored at room temperature up to 77°F (25°C), KALETRA oral solution should be used within two months.

Avoid exposure to excessive heat.

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 Fund

Abbott Fund is a philanthropic foundation established by Abbott in 1951. Abbott Fund's mission is to create healthier global communities by investing in creative ideas that promote science, expand health care and strengthen communities worldwide.

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 68,000 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. For more information on Abbott's HIV/AIDS programs, please visit www.abbott.com/hiv and www.abbottglobalcare.org.

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