

FOR IMMEDIATE RELEASE



## News

### Abbott Study Shows Investigational Heat-Stable Norvir® Tablet Provides Similar Drug Levels to Current Norvir Capsule

*Pivotal Study of Norvir Tablet Bioavailability Will Form the Basis of Request for Priority Regulatory Review*

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MEXICO CITY, Aug. 7, 2008 – Abbott presented pivotal data at the XVII International AIDS Conference (AIDS 2008) in Mexico City today showing that its investigational Norvir® (ritonavir) tablet and the current soft-gelatin capsule provide similar levels of drug in the blood.

The heat-stable Norvir tablet will not require refrigeration, making it more convenient for patients to use, particularly in developing countries where the majority of people with HIV live.

"The heat-stable formulation of ritonavir may help to further expand protease inhibitor-based HAART (highly active antiretroviral therapy) in regions where the need for refrigeration of HIV medicines is a major barrier to treatment and care," said Pedro Cahn, M.D., Ph.D., president, International AIDS Society.

The study compared the bioavailability of the 100mg ritonavir tablet to that of a 100mg soft-gelatin capsule under non-fasting conditions. The ritonavir tablet demonstrated similar bioavailability to the current soft-gelatin capsule, and was generally well tolerated. In this study performed on 93 healthy adult volunteers, the safety profiles of the two formulations were similar, with no serious adverse events reported.

Several formulations were evaluated, and the final formulation evaluated in the bioavailability study is the product of significant testing and formulation work. The data presented are the basis of upcoming regulatory submissions.

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Abbott has confirmed its intention to submit registration applications for the tablet and request priority review by U.S. and EU authorities before the end of the year and by Canadian authorities shortly thereafter.

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.

The Norvir tablet was developed using the Meltrex<sup>®</sup> technology, which was also used in the development of Abbott's Kaletra<sup>®</sup> tablets, which combine ritonavir and lopinavir. However, ritonavir on its own required a different formulation to ensure that the tablets remain stable over time and that the body can absorb the drug.

### **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 treatments around the world. Abbott has also made significant investments in expanding manufacturing capacity to meet the growing demand for HIV treatment in developing countries.

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 eight million rapid HIV tests to help prevent mother-to-child HIV transmission.

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Abbott and Abbott Fund have announced several efforts to expand access to treatment and care for children living with HIV/AIDS, including an additional investment of US\$12 million in grants and product donations this year.

For more information about Abbott's commitment to fighting HIV/AIDS, please visit [www.abbott.com/hiv](http://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](http://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 aged two years and older.

#### **Important Safety Information**

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

Norvir must not be taken in patients who have had a serious allergic reaction to Norvir or any of its ingredients.

Taking Norvir with certain medicines can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties or excessive sleepiness. Norvir must not be taken with Cordarone<sup>®</sup> (amiodarone); ergotamine, ergonovine, methylegonovine, and dihydroergotamines such as Cafergot<sup>®</sup>; Migranal<sup>®</sup>; D.H.E. 45<sup>®</sup> and others; Halcion<sup>®</sup> (triazolam); Hismanal<sup>®</sup> (astemizole); Orap<sup>®</sup> (pimozide); Propulsid<sup>®</sup> (cisapride); Quinidine<sup>®</sup>, also known as Quinaglute<sup>®</sup>; Cardioquin<sup>®</sup>; Quinidex<sup>®</sup>; Rythmol<sup>®</sup> (propafenone); Seldane<sup>®</sup> (terfenadine); Tambocor<sup>®</sup>; (flecainide); Uroxatral<sup>®</sup> (alfuzosin hydrochloride); Vascor<sup>®</sup> (bepridil); Versed<sup>®</sup> (midazolam); and Vfend<sup>®</sup> (voriconazole).

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Norvir must not be taken with St. John's Wort (*hypericum perforatum*), Mevacor® (lovastatin) or Zocor® (simvastatin).

The above lists of medicines are not complete. 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.

The most commonly reported side effects are: feeling weak or tired, nausea, vomiting, diarrhea, loss of appetite, abdominal pain, changes in taste, tingling feeling or numbness in hands or feet or around the lips, headache, and dizziness. This is not a complete list of reported side effects.

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).

Norvir oral solution should be stored at room temperature and should not be refrigerated.

Avoid exposing Norvir soft gelatin capsules and oral solution to excessive heat or cold. Store in the original container.

For more information about Norvir, please consult the prescribing information at [www.abbott.ca](http://www.abbott.ca).

### **About Kaletra**

#### **Indication**

Kaletra is indicated for the treatment of HIV-1 infected adults and children above the age of 6 months. 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.

#### **Important 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.

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Taking certain medications with Kaletra could create the potential risk for serious side effects that could be life threatening. Kaletra should not be taken with astemizole, cisapride, dihydroergotamine, ergonovine, ergotamine, lovastatin, methylergonovine, midazolam, pimozide, rifampin, simvastatin, St. John's wort, terfenadine, triazolam or vardenafil, as well as with a number of other medications. Consequently, patients should discuss with their doctor or pharmacist all medicines they are taking or plan to take, including those without a prescription and herbal preparations.

In Kaletra clinical trials, the most commonly reported side effects were abdominal pain, diarrhea, feeling weak or tired, headache, nausea, vomiting and rash. In children taking Kaletra, the safety profile is similar to that seen in adults.

This is not a complete list of reported side effects.

Kaletra oral solution contains alcohol.

For more information about Kaletra, please consult the prescribing information at [www.abbott.ca](http://www.abbott.ca).

#### **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.

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**Abbott Canada**, headquartered in Saint-Laurent, Quebec, employs approximately 1,200 people and ranks as one of the 50 Best Employers in Canada.

Abbott's news releases and other information are available on the company's Web sites at [www.abbott.ca](http://www.abbott.ca) and [www.abbott.com](http://www.abbott.com). For more information on Abbott's HIV/AIDS programs, please visit [www.abbott.com/hiv](http://www.abbott.com/hiv) and [www.abbottglobalcare.org](http://www.abbottglobalcare.org).

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