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Abbott Study Shows Investigational Heat-Stable Norvir(R) Tablet Provides Similar Drug Levels to Current Norvir Capsule

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Mexico City (ots/PRNewswire) - - Pivotal Study of Norvir Tablet Bioavailability Will Form the Basis of Request for Priority Regulatory Review

Abbott (NYSE: ABT) presented pivotal data at the XVII International AIDS Conference (AIDS 2008) in Mexico City today showing that its investigational Norvir(R) (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 in 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.

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.

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(R) technology, which was also used in the development of Abbott's Kaletra(R) 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.

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

<http://www.abbott.com/hiv>

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.

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(R) (amiodarone); ergotamine, ergonovine, methylergonovine, and dihydroergotamines such as Cafegot(R); Migranal(R); D.H.E. 45(R) and others; Halcion(R) (triazolam); Hismanal(R) (astemizole); Orap(R) (pimozide); Propulsid(R) (cisapride); Quinidine(R), also known as Quinaglute(R); Cardioquin(R); Quinidex(R); Rythmol(R) (propafenone); Seldane(R) (terfenadine); Tambocor(R); (flecainide); Uroxatral(R) (alfuzosin hydrochloride); Vascor(R) (bepridil); Versed(R) (midazolam); and Vfend(R) (voriconazole).

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

There are drug-drug interactions with the potential for risk of serious or life-threatening side effects. Alterations in dose, increased monitoring of drug levels in the blood or increased observations for side effects may be recommended when NORVIR is taken with: Lipitor(R) (atorvastatin), Crestor(R) (rosuvastatin), Viagra(R) (sildenafil), Cialis(R) (tadalafil), Levitra(R) (vardenafil), oral contraceptives ("the pill") or the contraceptive patch, Mycobutin(R) (rifabutin), rifampin, also known as Rimactane(R), Rifadin(R), Rifater(R) or Rifamate(R); inhaled Flonase(R) (fluticasone), metronidazole or disulfiram.

Rifampin and saquinavir should not be taken together with NORVIR. Patients should tell their doctor if they are taking rifampin and saquinavir.

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.

Pancreatitis and liver problems, which can be fatal, have been reported in patients receiving NORVIR. Patients should tell their doctor if they have nausea, vomiting, or abdominal pain, which may be signs of pancreatitis, or if they have or have had liver disease such as Hepatitis B or C.

Some patients have had large increases in triglycerides and cholesterol. Changes in body fat have been seen in some patients taking anti-HIV therapy. The long-term health effects of these conditions are not known at this time.

Diabetes and high blood sugar have occurred in patients taking protease inhibitors, such as NORVIR.

Some patients with hemophilia have increased bleeding with protease inhibitors.

The effects of NORVIR on pregnant women or to their unborn babies are not known. Mothers taking NORVIR should not breastfeed.

Refrigeration of NORVIR soft gelatin capsules by the patient is recommended, but not required if used within 30 days and stored below 77 degrees F (25 degrees 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.

Important Safety Information

KALETRA does not cure HIV-1 infection or AIDS and does not reduce the risk of passing HIV-1 to others.

KALETRA must not be taken by patients who have had an allergic reaction to KALETRA or any of its ingredients.

Taking KALETRA with certain drugs can cause serious problems or death. KALETRA must not be taken with dihydroergotamine, ergonovine, ergotamine or methylergonovines such as Cafegot(R), Migranal(R), D.H.E. 45(R), ergotrate maleate, and methergine, as well as Halcion(R) (triazolam), Orap(R) (pimozide), Propulsid(R) (cisapride), or Versed(R) (midazolam).

KALETRA must not be taken with rifampin, also known as Rimactane(R), Rifadin(R), Rifater(R), or Rifamate(R); St. John's Wort (*Hypericum perforatum*); Mevacor(R) (lovastatin), or Zocor(R) (simvastatin).

There are drug-drug interactions with the potential for risk of serious or life-threatening side effects. Alterations in dose, increased monitoring of drug levels in the blood, or increased observations for side effects may be recommended when KALETRA is taken with: Lipitor(R) (atorvastatin), Crestor(R) (rosuvastatin), Viagra(R) (sildenafil), Cialis(R) (tadalafil), Levitra(R) (vardenafil), oral contraceptives ("the pill") or the contraceptive patch, Mycobutin(R) (rifabutin), inhaled Flonase(R) (fluticasone), metronidazole, or disulfiram. Patients should talk with their doctor about all medicines they are taking or planning to take, including those without a prescription and herbal products.

KALETRA should not be given once-daily in combination with Sustiva(R) (efavirenz), Viramune(R) (nevirapine), Agenerase(R) (amprenavir), fosamprenavir, Viracept(R) (nelfinavir), phenobarbital, Dilantin(R) (phenytoin) or Tegretol(R) (carbamazepine).

Patients and/or their care providers should pay special attention to accurate administration of the KALETRA dose to reduce the risk of accidentally giving too much or too little medicine.

The most commonly reported side effects of moderate severity that are thought to be drug related are abdominal pain, abnormal bowel movements, diarrhea, feeling weak/tired, headache and nausea. Children taking KALETRA may sometimes get a skin rash. Other side effects may occur.

Pancreatitis and liver problems, which can be fatal, have been reported in patients receiving KALETRA. Patients should tell their doctor if they have nausea, vomiting, or abdominal pain, which may be signs of pancreatitis, or if they have or have had liver disease, such as hepatitis B or C.

Some patients have had large increases in triglycerides and cholesterol. Changes in body fat have been seen in some patients taking anti-HIV therapy. The long-term health effects of these conditions are not known at this time.

Diabetes and high blood sugar have occurred in patients taking protease inhibitors such as KALETRA.

Some patients with hemophilia have increased bleeding with protease inhibitors.

The effects of KALETRA on pregnant women or their unborn babies are not known. Mothers taking KALETRA should not breast-feed.

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 degrees F (25 degrees 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 <http://www.abbott.com> For more information on Abbott's HIV/AIDS programs, please visit <http://www.abbott.com/hiv> and <http://www.abbottglobalcare.org>

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