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New Abbott Aluvia(R) Tablet for Treatment of HIV Available in South Africa

Johannesburg, South Africa (ots/PRNewswire) -

- More than 5 Million South Africans Living with HIV Gain Access to First and Only Co-formulated, Non-refrigerated Protease Inhibitor

Abbott (NYSE: ABT) today announced that the new tablet formulation of its protease inhibitor Aluvia(R) (lopinavir/ritonavir), for the treatment of HIV-1, is now available to HIV/AIDS patients in South Africa -- a step the company hopes will positively impact millions of lives across the country.

"Today marks a new beginning for the treatment of HIV in South Africa," said Steven Miller, professor, Innovir Institute, Johannesburg, South Africa. "Millions of patients will now have the opportunity to benefit from a highly effective, co-formulated protease inhibitor that does not require refrigeration -- a critical step in advancing treatment and care in a country where HIV prevalence is among the highest in the world."

South Africa has experienced one of the most severe HIV/AIDS epidemics in the world. The Actuarial Society of South Africa estimates that, in 2006, almost half of all deaths in the country were caused by AIDS. Among adults aged 15-49 years, 71 percent of deaths were AIDS-related.

The lopinavir/ritonavir tablet (marketed as Aluvia in the developing world) is the first and only co-formulated protease inhibitor tablet that does not require refrigeration and can be taken with or without food -- two important advances in delivering HIV medicine, especially in developing countries. The tablet formulation also offers the increased dosing convenience of fewer pills (a total daily dose of four tablets, instead of six soft-gel capsules). Each Aluvia tablet contains 200 mg of lopinavir and 50 mg of ritonavir. The World Health Organization (WHO) has identified lopinavir/ritonavir as the recommended protease inhibitor for second-line therapy in resource-restricted countries, such as South Africa. Aluvia is always used in combination with other antiretroviral agents.

Abbott's introduction of the Aluvia tablet in South Africa is part of its five-point global strategy to expand access to HIV treatments around the world by:

- Continuing to innovate with an eye on the needs of the developing world;
- Investing in manufacturing capacity to ensure consistent, quality supply;
- Offering tiered and affordable pricing;
- Broadening registration of life-enhancing medicines; and
- Focusing on pediatric HIV care.

"Bringing a heat-stable tablet version of lopinavir/ritonavir to South Africa is another example of Abbott's commitment to working with the business community and health community to improve health systems and address challenges of capacity building and access in Africa and beyond," said Scott Brun, M.D., divisional vice president, infectious diseases and immunology development, Global Pharmaceutical Research and Development, Abbott.

Lopinavir/ritonavir has been available in soft-gel capsules (known as Kaletra(R)) and as an oral solution since it was first

approved in the United States in September 2000. Using its breakthrough Meltrex(TM) technology, Abbott developed the tablet formulation, which maintains a similar safety and efficacy profile as the soft-gel capsule. The tablet formulation received approval from the U.S. Food and Drug Administration in 2005 and the European Medicines Agency in 2006.

Progress on Global Registration of Lopinavir/Ritonavir Tablets

Abbott has worked diligently to register the tablet around the world. Today, the tablet is filed, available (where no regulatory approval is needed) or approved in 154 countries. The original lopinavir/ritonavir capsule is registered in 118 countries, making it the most widely registered HIV medicine in the world (according to WHO data).

The lopinavir/ritonavir tablet is now filed, available or approved in nearly every African country (48 countries), where the majority of the world's people with HIV live. In addition to South Africa, the tablet is available or approved in: Angola, Benin, Botswana, Cameroon, Camoros, Central African Republic, Congo Brazzaville, Cote d'Ivoire, Djibouti, DR Congo, Ethiopia, Gabon, Ghana, Guinea Conarkry, Kenya, Lesotho, Libya, Malawi, Mauritius, Mauritania, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Swaziland, Tanzania, Togo, Uganda and Zambia.

Availability of Lower-Strength Lopinavir/Ritonavir Tablets

Abbott also has filed its lower-strength lopinavir/ritonavir tablet, suitable for pediatric use, in South Africa. This new formulation represents a significant advancement for clinicians and patients in developing countries, where more than 2 million of the estimated 2.5 million children with HIV/AIDS under 15 years of age, worldwide, lived in 2007. The lower-strength tablet formulation contains 100 mg of lopinavir and 25 mg of ritonavir. The lower-strength tablet is filed, available or approved in more than 80 countries around the world. Abbott intends to make the lower-strength tablet available or approved in 155 countries around the world, just as it will with the adult tablet.

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 8 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 Aluvia

Indication and Important Safety Information for lopinavir/ritonavir

Indication

Aluvia is indicated for the treatment of HIV-1 infected adults and children above the age of 2 years. It is used in combination with other antiretroviral agents.

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

Important Safety Information

Aluvia should not be taken by patients who have had an allergic reaction to any of its ingredients, including lopinavir or ritonavir, or any of the excipients, or by patients with severe liver problems.

Taking certain medications with Aluvia could cause serious side effects that could be life threatening. Do not take Aluvia with astemizole, terfenadine, midazolam, triazolam, pimozide, cisapride, ergotamine, dihydroergotamine, ergonovine, methylergonovine, rifampicin, amiodarone, vardenafil and products containing St. John's Wort (*Hypericum perforatum*).

Medical advice and approval must be sought before Aluvia is taken with medicines that lower blood cholesterol (e.g., lovastatin or simvastatin), some medicines affecting the immune system (e.g., cyclosporin, sirolimus [rapamycin], tacrolimus), various steroids (e.g., dexamethasone, fluticasone propionate, ethinyl oestradiol), other protease inhibitors, certain heart medicines such as calcium channel antagonists, (e.g., felodipine, nifedipine, nicardipine) and medicines used to correct heart rhythm (e.g., bepridil, systemic lidocaine, quinidine), antifungals, (e.g., ketoconazole, itraconazole), morphine-like medicines (e.g., methadone), anticonvulsants (e.g., carbamazepine, phenytoin, phenobarbital), warfarin, certain antibiotics (e.g., rifabutin, clarithromycin), certain antidepressants (e.g., trazodone) and voriconazole.

Aluvia may interact with erectile dysfunction agents (e.g., sildenafil or tadalafil). Lower doses of these medicines should be prescribed in patients taking Aluvia.

Aluvia may interact with digoxin (heart medicine); monitoring by a physician is recommended.

Taking Aluvia with certain medicines can cause increased levels of these other medicines in the body. This could increase or prolong their effects and/or adverse reactions, which may result in serious or life-threatening problems. Because of this, patients must tell their doctor about all medicines they are taking or planning to take, including those medicines that can be bought without a prescription and herbal preparations.

Patients using an oral contraceptive or using a patch contraceptive to prevent pregnancy should use an additional or alternative type of contraception since Aluvia may reduce the effectiveness of these products.

Pregnant or nursing mothers should not take Aluvia unless specifically directed by their doctor.

Aluvia tablets may be taken with or without food.

Cases of pancreatitis have been reported in patients taking lopinavir/ritonavir. Liver problems, which can be fatal, have also been reported. Patients should tell their doctor if they have had liver disease such as chronic hepatitis B or C as they are at

increased risk for severe and potentially fatal liver adverse events. These patients may require blood tests for control of liver function.

Redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Patients should contact their doctor if they notice changes in body fat.

In patients taking protease inhibitors, increased bleeding (in patients with hemophilia type A and B) has been reported.

Combination antiretroviral therapy may cause new cases of diabetes and high blood sugar or worsening of existing diabetes, as well as increased fats and raised lactic acid in the blood. The long-term risks for complications due to increases in triglycerides and cholesterol are not known at this time. In addition, large amounts of triglycerides have been considered a risk factor for pancreatitis.

In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. Symptoms of infection should be reported to a doctor immediately.

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis. Signs and symptoms are joint stiffness, aches and pains (especially in the hip, knee and shoulder) and difficulty in movement. These symptoms require that patients contact their doctor.

In lopinavir/ritonavir adult clinical trials, the very common and commonly reported side effects of moderate to severe intensity were diarrhea, insomnia, headache, nausea, vomiting, abdominal pain, abnormal stools, dyspepsia, flatulence, gastrointestinal disorder, rash, lipodystrophy, weakness and abnormal liver enzymes. This is not a complete list of reported side effects.

In children 2 years of age and older, the safety profile is similar to that seen in adults.

For more information about Aluvia, please consult your local prescribing information.

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Storage Conditions:

Aluvia tablets do not require any special storage conditions.

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/HIVAIDS> and <http://www.abbottglobalcare.org>.

Web site: <http://www.abbott.com>
<http://www.abbottglobalcare.org>

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