

For Immediate Release



News

Abbott's Kaletra[®] Tablet Dosed Once-Daily or Twice-Daily Demonstrated Similar Clinical Results Across Race and Gender Lines

HIV-Infected Women and Non-Whites New to Antiretroviral Therapy Respond Similarly to Men and Whites

MEXICO CITY, Aug. 5, 2008 – Initial treatment regimens containing once-daily or twice-daily dosing of Abbott's protease inhibitor Kaletra[®] (lopinavir/ritonavir) tablet provided similar results for controlling the virus (reducing the amount of HIV-1) and improving the immune system (increasing CD4 cells) in women compared to men and in non-whites compared to whites, according to 48-week data presented by Abbott today at the XVII International AIDS Conference (AIDS 2008).

A retrospective sub-analysis of study M05-730 at week 48 of 96 weeks offered data on the impact of gender and race on a Kaletra-based regimen. Women and non-whites have traditionally been underrepresented in HIV studies, although these patient groups increasingly account for the vast majority of HIV infections. According to the World Health Organization, by the end of 2007, 22.5 million of the total 33.2 million people infected with HIV lived in sub-Saharan Africa. Additionally, 15.4 million of the total number of HIV-infected patients worldwide are women.

"The results showed that regardless of gender or race, Kaletra dosed once-daily or twice-daily as part of a treatment regimen achieved consistent virologic suppression in patients new to antiretroviral therapy," said Scott Brun, M.D., divisional vice president, Infectious Diseases and Immunology Development, Global Pharmaceutical Research and Development, Abbott. "Additionally, the Kaletra tablet formulation is a convenient HIV treatment option that can be taken with or without food and does not require refrigeration, which is particularly important to patients in the developing world who are disproportionately affected by HIV."

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M05-730 Analysis Results

Through 48 weeks, the proportions of males and females who achieved an undetectable HIV viral load were similar. In addition, the proportions of whites and non-whites who achieved an undetectable HIV viral load were similar. Specifically, 72 percent of women and 78 percent of men, and 75 percent of non-whites and 77 percent of whites had undetectable HIV viral loads (less than 50 copies/mL) at 48 weeks.

CD4+ cell count mean increases over 48 weeks were similar for females and males, independent of baseline CD4+ cell count, except among women with baseline CD4+ cell counts of fewer than 50 cells/mm³, who experienced statistically significant greater mean increases in CD4+ cell counts than males. In addition, CD4+ cell count mean increases over 48 weeks were similar for whites and non-whites. At 48 weeks, the overall rate of moderate to severe and related adverse events of diarrhea was 15.8 percent. A similar rate of diarrhea was observed in whites (17.8 percent), while non-whites experienced a rate of 9.7 percent.

"This sub-analysis of M05-730 provides additional clinical information on race and gender response with Kaletra," said Joseph Gathe, Jr., M.D., clinical instructor, Department of Internal Medicine, Baylor College of Medicine. "The information can help physicians in making treatment decisions for the patient populations most affected by HIV."

About the M05-730 Study – 48-week Data

Design and Primary Endpoints:

- M05-730 study is a 96-week Phase III open-label, randomized, multi-center, multi-country study that enrolled 664 ARV-naïve patients with HIV-1 RNA \geq 1000 copies/mL and any CD4+ T-cell count. Patients were randomized equally to lopinavir/ritonavir 800/200 mg once-daily soft gel capsule (SGC), 400/100 mg twice-daily (BID) SGC, 800 mg/200 mg once-daily tablet or 400/100 mg twice-daily tablet for eight weeks. All patients also received emtricitabine (FTC) 200 mg once-daily and tenofovir disoproxil fumarate 300 mg once-daily. At week eight, all patients receiving SGC were switched to the tablet formulation of Kaletra, matching their previous dosing schedule of once- or twice-daily.

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- The primary efficacy endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL at week 48, using an intent to treat noncompleter equals failure approach comparing once-daily and twice-daily groups. A secondary efficacy endpoint was mean change from baseline in CD4+ T-cell count.
- The primary safety endpoint was the proportion of patients reporting a treatment-emergent adverse event of diarrhea during the first eight weeks of dosing. Additional safety analyses included the proportion of subjects reporting treatment-emergent adverse events, grade 3+ lab abnormalities, and mean changes from baseline for lab determinations through 48 weeks.

Primary Efficacy Results:

- At week 48, the primary efficacy analysis showed that 77 percent of the once-daily-treated patients and 76 percent of the twice-daily treated patients achieved a viral load <50 copies/mL. The once-daily regimen was determined to be non-inferior to the twice-daily regimen.
- Through week 48, 14.7 percent and 16.6 percent of the patients discontinued treatment on the once-daily and twice-daily regimens, respectively. A similar percentage of patients on the once-daily regimen discontinued due to adverse events, as on the twice-daily regimen (4.8 percent and 3 percent, respectively).
- With respect to the comparison of the SGC to the tablet formulation through week eight, there were no statistically significant differences in the following areas: the number of patients discontinuing due to gastrointestinal adverse events or other adverse events; the incidence of treatment-emergent adverse events of diarrhea of any severity and of moderate or greater severity and related to the study drug; the proportion of patients with Grade 3+ lab abnormalities; or the mean change from baseline for total cholesterol or triglycerides at any time point during the first eight weeks of treatment.
- The most common moderate/severe related adverse events in the once-daily and twice-daily groups respectively were: diarrhea (17 percent versus 15 percent), nausea (seven percent versus five percent), vomiting (three percent versus four percent), and increased triglycerides (two percent in both groups). There was no statistical difference between the groups.

- At week 48, the overall impact of Kaletra, dosed once-daily or twice-daily, on grade 3-4 lab abnormalities, including cholesterol and triglycerides, the liver enzymes, SGOT/AST, and creatinine clearance was similar.
- At week 48, there was a statistically significant difference in the increase of total cholesterol between the once-daily and twice-daily group.

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 www.abbott.com/hiv.

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 6 months and older.

Important Safety Information

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

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 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.

Storage Conditions

Kaletra tablets should be stored between 15 and 25° C.

Kaletra oral solution should be stored in a refrigerator (2 - 8° C). If kept outside of the refrigerator, do not store above 25° C and discard any unused contents after 42 days (6 weeks). 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 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 and 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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