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Head-to-Head Study Comparing LEXIVA(R) (fosamprenavir calcium) to Kaletra Presented at IAC 2006 and Published in The Lancet

LEXIVA(R)/r Twice-Daily Provided Comparable Efficacy to Kaletra Twice-Daily in Treatment-Naive HIV Patients

Toronto, Canada, August 17, 2006 -- This month, The Lancet published results of a study showing that HIV regimens using LEXIVA (Telzir) Tablets+ritonavir and Kaletra (lopinavir/ritonavir) Capsules both given twice-daily had comparable (non-inferior) efficacy and tolerability in adults who had no previous exposure to HIV medicines. Parts of this study were also presented at this week's International AIDS Conference in Toronto, Canada.

The publication of the 48-week clinical study known as KLEAN (Kaletra vs. LEXIVA with Epivir(R) (lamivudine) and Abacavir in ART-Naive patients) was announced today by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX), the companies that co-discovered LEXIVA. LEXIVA is indicated for the treatment of HIV infection in adults in combination with other antiretroviral medications. Once-daily administration of LEXIVA/r is not recommended for PI-experienced patients.

"Protease inhibitors continue to be a key component of antiretroviral therapy and this new information reinforces the efficacy and safety of LEXIVA/r for treatment-naive patients with HIV," said Joseph Eron, Jr., MD, Professor of Medicine, Division of Infectious Diseases, University of North Carolina at Chapel Hill.

Study Explained
The publication reported results from the KLEAN study, a randomized, open-label, multicenter, international Phase IIIb trial comparing LEXIVA/r twice-daily to lopinavir/r twice-daily in treatment-naive patients. The study included 878 patients with HIV-1 RNA (vRNA) >1,000 copies/mL (c/mL) and any CD4+ cell count during the pre-trial screening. Patients were randomized to receive either LEXIVA/r or lopinavir/r twice daily, administered with Epzicom(TM) (abacavir/lamivudine) once daily, with 434 patients in the LEXIVA/r arm and 444 in the lopinavir/r arm.

Primary endpoints were the proportion of subjects with vRNA <400 c/mL at week 48 and treatment discontinuations due to adverse events. These results were analyzed according to intent to treat exposed TLOVR (Time to Loss of Virologic Response). Protocol-defined virologic failure was defined as failure to achieve HIV RNA <400 c/mL by week 24 or confirmed rebound >400 c/mL. Seventy-seven percent of the patients (676) completed the study, with 12 percent and 10 percent of patients discontinuing treatment due to adverse events in the LEXIVA/r and Kaletra arms, respectively.

LEXIVA/r administered twice-daily was shown to be non-inferior to lopinavir/r given twice-daily over 48 weeks. At 48 weeks, 73 percent (315) of the patients treated with LEXIVA/r achieved vRNA <400 c/mL, and 71 percent (315) of the patients in the lopinavir/r arm achieved this measurement by week 48. At 48 weeks, 66 percent (285) of the patients treated with LEXIVA/r and 65 percent (288) of the lopinavir/r patients achieved vRNA <50c/mL. The median CD4 cell increase in patients at 48 weeks was 176 c/ml in patients who received LEXIVA/r and 191 c/ml in patients who received lopinavir/r.

The most frequently reported drug related Grade 2 - 4 adverse events reported in the study included diarrhea (13 percent, 11 percent), nausea (6 percent, 5 percent) and abacavir hypersensitivity reaction (6 percent, 4 percent) in the study arms containing LEXIVA/r and lopinavir/r, respectively. Similar increases in fasting lipid values were also observed in both regimens. Adverse events in this study were consistent with those described in the product information for LEXIVA and Kaletra.

Lexiva Indication Statement and Background
LEXIVA is indicated for the treatment of HIV infection in adults in combination with other antiretroviral medications. The following points should be considered when initiating therapy with LEXIVA plus ritonavir (LEXIVA/r) in PI-experienced patients: the PI-experienced patient study was not large enough to reach a definitive conclusion that LEXIVA/r and lopinavir/ritonavir are clinically equivalent. Once-daily administration of LEXIVA plus ritonavir is not recommended for PI-experienced patients.

LEXIVA was co-discovered by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated. LEXIVA was approved by the FDA for use in the US in 2003.

IMPORTANT Safety Information About LEXIVA

HIV medicines do not cure HIV infection/AIDS or prevent passing HIV to others.

Patients should not take LEXIVA if they have had an allergic reaction to LEXIVA or AGENERASE(R) (amprenavir). High blood sugar, diabetes or worsening of diabetes, and bleeding in hemophiliacs have occurred in some patients taking protease inhibitors. When a patient starts taking HIV medicines, his immune system may get stronger and could begin to fight infections that have been hidden in his body, such as pneumonia, herpes virus, or tuberculosis. If a patient has new symptoms after starting his HIV medicines, he should tell his doctor. Changes in body fat may occur in some patients taking antiretroviral therapy. The cause and long-term health effects of these conditions are not known at this time. Skin rashes can occur in patients taking LEXIVA. Rarely, rashes were severe or life threatening. Opportunistic infections can develop when a patient has HIV and his immune system is weak. It is very important that patients see their healthcare provider regularly while taking LEXIVA to discuss any side effects or concerns. Most common side effects in clinical studies were diarrhea, headache, nausea, rash, and vomiting. In most cases, these side effects did not cause people to stop taking their medicine.

For full prescribing information for LEXIVA, please visit www.treathiv.com

About GlaxoSmithKline GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies and an industry leader in HIV research and therapies. The company is engaged in basic research programs designed to investigate new targets to treat HIV. For full prescribing information please go to www.LEXIVA.com.

GSK's Bridges to Access program can help provide qualified individuals with access to GSK's antiretroviral medications, as well as help identify insurance or other support for medications. Patients may be eligible for this program if they are not eligible for prescription drug benefits through any other private or public insurer, payer or program. In 2004, GlaxoSmithKline donated more than $372.5 million worth of prescription drugs to 475,000 patients. For more information, visit www.bridgestoaccess.gsk.com or call 1-866-PATIENT.

About Vertex
Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration with major pharmaceutical companies. Vertex's product pipeline is principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

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