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Vertex Pharmaceuticals and GlaxoSmithKline Announce Virologic and Drug Resistance Results from Protease Inhibitor Study

San Francisco, CA, September 28, 2006 -- Data presented today show low rates of virologic failure and antiviral drug resistance with the HIV protease inhibitor LEXIVA boosted with ritonavir (LEXIVA/r). The virologic analysis from a 48-week study in treatment naive patients, compared Lexiva/r to lopinavir/r, both administered twice daily, and showed that virologic failure was uncommon (5 percent) and that treatment-emergent antiviral drug resistance was not observed with either treatment arm.

These data were announced today at the 46th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated, 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.

"These data reinforce the resistance profile associated with boosted LEXIVA," said Denise Sutherland-Phillips, MD, Manager and Medical Monitor, Clinical Development, HIV Infectious Disease Medicine Development Center at GSK. "We did not observe any treatment-emergent mutations in either treatment arm and there was no reduced susceptibility to the PIs. This subanalysis suggests that the resistance profile is equivalent between the two medications."

KLEAN Study Background
Data comparing the safety and efficacy of LEXIVA/r to lopinavir/r were published in the August 5, 2006 issue of The Lancet. The primary efficacy and safety analyses from this study, known as KLEAN (Kaletra® [lopinavir/ritonavir] vs. LEXIVA with Epivir® (lamivudine) and Abacavir in ART-Naive patients) were also presented at the International AIDS Conference in Toronto in August 2006. This randomized, open-label, multicenter, international phase IIIb trial is the first to compare LEXIVA/r to lopinavir/r in treatment-naive patients. The study included 878 treatment-naive patients with HIV-1. Patients were randomized to receive either LEXIVA/r or lopinavir/r twice daily, administered with Epzicom‰ (abacavir sulfate and lamivudine) once daily. Study results at 48 weeks showed that an HIV regimen containing LEXIVA/r administered twice-daily had comparable (non-inferior) efficacy and tolerability to lopinavir/r twice daily in treatment-naive adults.

Data Overview
The analysis of the KLEAN study presented at ICAAC describes the virologic response and resistance patterns associated with virologic failure. At 48 weeks, four percent of the patients in the LEXIVA/r arm (n=434) and five percent of the patients in the lopinavir/r arm (n=444) experienced virologic failure, which was defined as either a failure to achieve plasma HIV-1 RNA (vRNA) <400c/mL by week 24, or confirmed rebound in vRNA to > 400 c/mL. Of the 40 patients who had confirmed virologic failure, ten failed to achieve the designated plasma levels, and 30 experienced viral rebound.

The emergence of viral mutations and reduction in drug susceptibility were evaluated by the PhenoSense GT assay at baseline and time of confirmed virologic failure. Virus from 26 out of 37 subjects showed no treatment-emergent mutations at the time of confirmed virologic failure. The most common treatment-emergent mutations seen were NRTIs (n=7), PIs (n=4), and NNRTI (n=2). No differences were seen between the two treatment arms with respect to emergence of on-treatment genotypic resistance. Although four PI mutations emerged during treatment, they did not confer reduced susceptibility to fosamprenavir or lopinavir.

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 (RTV) (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 RTV is not recommended for PI-experienced patients.

LEXIVA was co-discovered by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated. It is the first PI to offer flexible dosing options (for PI-naive patients) with no food or water restrictions. LEXIVA is indicated in combination with other antiretroviral agents for the treatment of HIV infection in adults.

Important Safety Information about LEXIVA
HIV medicines do not cure HIV infection/AIDS or prevent passing HIV to others.

LEXIVA is contraindicated in patients with previously demonstrated clinically significant hypersensitivity to any of the components of this product or to amprenavir. Hyperglycemia, new onset or exacerbations of diabetes mellitus, and spontaneous bleeding in hemophiliacs have been reported with protease inhibitors.

Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The causal relationship, mechanism and long-term consequences of these events are currently unknown.

LEXIVA should be used with caution in patients with a known sulfonamide allergy.

Severe or life-threatening skin reactions were reported in less than 1 percent of 700 patients treated with LEXIVA in clinical studies, including one case of Stevens-Johnson syndrome.

Skin rashes (all grades, without regard to causality) occurred in approximately 19 percent of patients treated with LEXIVA in the pivotal efficacy studies. This led to the discontinuation of LEXIVA in less than 1 percent of patients.

During the initial phase of treatment, patients responding to antiretroviral therapy may develop an inflammatory response to indolent or residual opportunistic infections.

LEXIVA is contraindicated with ergot derivatives, cisapride, pimozide, midazolam and triazolam. If LEXIVA is coadministered with ritonavir, flecainide and propafenone are also contraindicated. Caution should be used when coadministering medications that are substrates, inhibitors or inducers of CYP3A4, or potentially toxic medications that are metabolized by CYP3A4. Serious and/or life-threatening drug interactions could occur between LEXIVA and amiodarone, lidocaine (systemic), tricyclic antidepressants and quinidine. Concentration monitoring of these agents is recommended if these agents are used concomitantly with LEXIVA. LEXIVA should not be coadministered with rifampin, St. John's wort, lovastatin, simvastatin or delavirdine. Particular caution should be used when prescribing phosphodiesterase (PDE-5) inhibitors for erectile dysfunction (e.g., sildenafil or vardenafil) in patients receiving LEXIVA. This list of potential drug interactions is not complete.

Treatment with LEXIVA/r has resulted in an increase in the concentration of triglycerides. Triglyceride and cholesterol testing should be performed prior to initiating therapy with LEXIVA and at periodic intervals during therapy. The most common adverse events seen in clinical trials with LEXIVA were diarrhea, nausea, vomiting, headache and rash.

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.

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 focused on viral diseases, inflammation, autoimmune diseases, cancer, pain and bacterial infection. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Safe Harbor Statement
This press release may contain forward-looking statements. While management makes its best efforts to be accurate in making forward-looking statements, such statements are subject to risks and uncertainties that could cause Vertex's actual results to vary materially. These risks and uncertainties include, among other things, the risks that full analysis of the data, including an ongoing detailed safety analysis, or further testing, will not reflect the preliminary results reported in this press release, or support any or all of the conclusions provided in this press release; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

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