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Long-Term Safety Data of Lexiva/r in HIV Patients Co-Infected with Hepatitis

- Combination of Lexiva/r and Truvada Evaluated -

Rio de Janeiro, Brazil - July 26, 2005 - HIV patients with hepatitis C (HCV) or B (HBV) had no negative effect to liver enzymes through 120 weeks of treatment (n=35) with a once-daily (QD) dose of LEXIVA(R) (fosamprenavir calcium) boosted with ritonavir (LEXIVA/r) as part of an antiretroviral regimen. These data were from a retrospective analysis of a subset of patients in study APV30002/APV30005 and were presented here today at the 3rd Annual International AIDS Society (IAS) Conference on HIV Pathogenesis and Treatment. There are no data on the use of Lexiva in combination with ritonavir in patients with any degree of hepatic impairment.

"It is encouraging that the liver enzymes remained stable in co-infected patients," said Mark Shaefer, Pharm. D., Acting Vice President, HIV, Infectious Disease Medicine Development Center at GlaxoSmithKline.

LEXIVA is an HIV protease inhibitor (PI) that was co-discovered by GlaxoSmithKline (GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX). It is the first PI with flexible dosing and no food or water restrictions.

LEXIVA is indicated in combination with other antiretroviral agents for the treatment of HIV infection in adults. The following points should be considered when initiating therapy with 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.

Among results of the 120-week analysis presented at IAS:

- Median decreases of -5 u/L alanine aminotransferase (ALT) and -9 u/L aspartate aminotransferase (AST) were observed among 35 patients with HCV or HBV infection. ALT and AST are enzymes that, when elevated, may be markers for liver disease.
- Median decreases of -8 u/L in ALT and -8 u/L in AST were observed among 134 patients without hepatitis co-infection.
- There were few new treatment-emergent Grade 3-4 ALT or AST toxicities observed between week 48 and week 120.
- The incidence of adverse events was comparable between patients co-infected with hepatitis and those without co-infection.

The 48-week data are from the SOLO trial, an open-label, multi-center study evaluating the safety and efficacy of QD dosing of LEXIVA/r in 649 treatment-naive patients. LEXIVA/r was administered as part of a regimen that also included abacavir sulfate (ABC) and lamivudine (3TC). The study presented at IAS analyzed data from patients who completed 48 weeks of treatment in the SOLO study and were enrolled in an ongoing study (APV30005) of long-term treatment results.

"Approximately 25 percent of HIV patients in the developed world are co-infected with HCV or HBV, and effective antiretroviral therapy has been associated with slower progression of liver disease," said Edwin DeJesus, M.D., study investigator, Orlando Immunology Center, Orlando, Florida. "Safety data from long-term trials such as SOLO and APV30005 - especially with regard to liver toxicity - are important information in optimizing treatment for HIV patients."

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 (eg, sildenafil or vardenafil) in patients receiving LEXIVA. This list of potential drug interactions is not complete.

Treatment with LEXIVA/r has resulted in increases 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.

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-promotes the HIV protease inhibitor, Lexiva(R), with GlaxoSmithKline.

Vertex 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 those risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2005.

Lexiva(R) is a registered trademark of the GlaxoSmithKline group of companies.

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