November 18, 2005

FDA Approves Updated Labeling for LEXIVA

- Coadministration With Esomeprazole Does Not Affect Blood Levels of LEXIVA -

Cambridge, MA and Research Triangle Park, NC, November 18, 2005- GlaxoSmithKline (NYSE: GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) approved GSK's application to add clinical data to the prescribing information for LEXIVA(R) (fosamprenavir calcium), an HIV protease inhibitor (PI). The newly added information shows that simultaneous administration of LEXIVA in combination with esomeprazole (Nexium(R)) does not result in lowering of blood levels for LEXIVA. This update is based on a study showing that blood levels of LEXIVA remained unchanged when patients took LEXIVA and 20 mg once-daily esomeprazole simultaneously. Drug interactions that result in lower PI blood levels may increase the risk for virologic failure in patients treated with HIV protease inhibitors.

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 is the first PI to offer flexible dosing options with no food or fluid restrictions.

Among HIV-positive patients, heartburn, gastroesophageal reflux disease and ulcers are common disorders. A recent survey of 200 HIV-positive patients found that nearly 80 percent of patients have used an over the counter (OTC) acid-reducing agent and 39 percent have used a prescription proton pump inhibitor (PPI)1. In the month prior to the survey, 28 percent reported using an antacid, 25 percent used a prescription PPI and 13 percent used an OTC acid-reducing agent including OTC PPIs.

"To avoid potential drug interactions, it is important that patients talk with their health care professional about any medications, even over-the-counter products, they are taking," said Mark Shaefer, Pharm. D., acting vice president, HIV, Infectious Disease Medicine Development Center at GSK. "With this update, patients know that they can take a proton pump inhibitor simultaneously with LEXIVA without affecting blood levels of LEXIVA."

LEXIVA was co-discovered by GlaxoSmithKline and Vertex Pharmaceuticals Incorporated.

The new prescribing information includes data from study APV10031, a randomized, open-label, cross-over study in 48 healthy adults. Subjects received 20 mg of esomeprazole alone for seven days followed by the addition of 1400 mg LEXIVA BID (twice-a-day) or 700 mg LEXIVA boosted with 100 mg ritonavir (r) BID for 14 days at the same time with their dose of esomeprazole. This was followed by a 21 to 28-day washout period and then participants were given unboosted or boosted LEXIVA for 14 days. Results indicated that blood levels of LEXIVA were not changed when taken simultaneously with esomeprazole compared to LEXIVA administered without esomeprazole. Blood levels of esomeprazole were increased by 55 percent when taken with 1400 mg LEXIVA BID.

Proton pump inhibitors such as esomeprazole reduce levels of stomach acid and are used to treat several stomach problems including heartburn. Over-the-counter antacids also reduce levels of stomach acid and, when coadministered with LEXIVA, did not significantly affect the blood levels of LEXIVA.

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 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 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, with GlaxoSmithKline.

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.

1HIV+ Patient Survey, Ziment Chronic Disease Sufferers Panel, April-May 2004

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.

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