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Viral Suppression of Once-Daily LEXIVA Plus Ritonavir Sustained Over 120 Weeks in ART-naive Subjects, According to Study Presented at DART

Montego Bay, Jamaica, December 15, 2004 -- The protease inhibitor (PI) LEXIVA(R) (fosamprenavir calcium) plus ritonavir (LEXIVA/r) dosed once daily (QD) demonstrated sustained viral suppression and safety over 120 weeks, according to data presented here today at the Frontiers in Drug Development for Antiretroviral Therapies (DART) conference. The findings are from study APV30005, a rollover study that enrolled 211 patients who completed 48 weeks of treatment in the SOLO study (APV30005) with LEXIVA/r QD in combination with abacavir and lamivudine twice daily. Results of the study were based on Observed and Missing or Discontinuation=Failure (MD=F) analyses.

LEXIVA was co-discovered by GlaxoSmithKline (GSK) and Vertex Pharmaceuticals (Nasdaq: VRTX).

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

Study APV30005
Undetectable viral load (VL) (<400 copies/mL) was observed at 120 weeks in 159 of 171 subjects (93 percent, Observed) and 159 of 211 subjects (75 percent, MD=F) taking LEXIVA/r. Other findings at 120 weeks:

- No primary or secondary PI mutations were observed in patients who had no baseline mutations and who experienced virologic failure (>1,000 copies/mL).
- CD4 cells increased a median of 292 cells/mm3 from baseline median of 168 cells/mm3
- 91 of 98 patients (93 percent, Observed) and 91 of 120 patients (76 percent MD=F) with low baseline (BL) CD4 counts (<200 cells/mm3) achieved undetectable VL, and 32 of 33 (97 percent, Observed) and 32 of 42 (76 percent, MD=F) with BL CD4 <50 cells/mm3 achieved undetectable VL (Observed).

"This analysis concluded that long-term treatment with LEXIVA/r resulted in sustained viral suppression, continued increase in CD4 cell count, no selection of PI resistance in virologic failures, and no new safety concerns," said Joe Gathe, M.D., clinical instructor, department of internal medicine, Baylor College of Medicine, Houston.

Lipodystrophy Data at 120 Weeks
The data presented at DART complement 120-week data presented at the International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV, which found no increase in the proportion of patients with fat redistribution or wasting between week 48 and week 120 among ART-naive patients taking LEXIVA/r QD. Of the patients with no body composition changes at baseline, fat redistribution was reported by 34/180 (19 percent) at week 48 and 29/156 (19 percent) at week 120. This study included 211 treatment-naive patients from the SOLO trial who continued taking LEXIVA/r through 120 weeks (Study APV30005).

A median increase of 4 kg in body weight was observed from baseline to 120 weeks (n=170), and there was no median change in waist/hip ratio. 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 may be dosed three different ways in ART-naive patients: 1) two 700 mg tablets twice daily (BID), 2) two 700 mg tablets once daily (QD) in combination with two 100 mg capsules of ritonavir QD (LEXIVA/r QD), or 3) one 700 mg tablet BID in combination with one 100 mg capsule of ritonavir BID (LEXIVA/r BID). For PI-experienced patients, the recommended dose is one 700 mg tablet BID in combination with one 100 mg capsule of ritonavir BID.

The FDA approval of LEXIVA was based on experience in more than 1,200 HIV-infected people - both ART-naive and PI-

experienced patients - who participated in three pivotal Phase III trials to test the safety and efficacy of LEXIVA with and without ritonavir. In all three trials, study drugs were taken as part of combination therapy that included two nucleoside reverse transcriptase inhibitors.

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.

LEXIVA is contraindicated with ergot derivatives, cisapride, pimozide, midazolam and triazolam. If LEXIVA is co-administered with ritonavir, flecainide and propafenone are also contraindicated. The most common adverse events seen in clinical trials with LEXIVA were diarrhea, nausea, vomiting, headache and rash. 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.

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.treathiv.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 2003, GlaxoSmithKline donated more than $205 million worth of prescription drugs to 400,000 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 partners. 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.

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

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 15, 2004 and amended on September 8, 2004.

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