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Study Evaluates Effectiveness of LEXIVA/ritonavir and Lopinavir/ritonavir in Protease Inhibitor (PI)- Experienced Patients 48-Week Data Presented at IAC

Bangkok, July 12, 2004 -- HIV treatment regimens containing the protease inhibitor (PI) LEXIVA(R) (fosamprenavir calcium) dosed with ritonavir (LEXIVA/r) or lopinavir (LPV) and ritonavir (LPV/r) were effective in suppressing HIV in patients who had failed prior PI-containing regimens, according to information presented here today at the International AIDS Conference (IAC). Lexiva was co-discovered by GlaxoSmithKline (GSK) and Vertex Pharmaceuticals (Nasdaq: VRTX).

The data are based on 48-week results of the CONTEXT study, a Phase III clinical trial that enrolled patients who had experienced virologic failure (VF) while receiving one to two prior PI regimens. Patients were randomized to take one 700mg LEXIVA tablet and one 100mg capsule of ritonavir (LEXIVA/r) twice a day (BID) (four capsules daily), 1400mg Lexiva plus 200mg ritonavir once a day (QD), or three LPV/r capsules, each combining 400mg LPV and 100mg of ritonavir BID (six capsules daily). PIs were taken in combination with two nucleoside reverse transcriptase inhibitors (NRTIs).

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 LPV/r are clinically equivalent.

Once-daily administration of LEXIVA dosed with ritonavir is not recommended for PI-experienced patients, who are advised to take one 700mg tablet of LEXIVA BID in combination with one 100mg capsule of ritonavir BID.

At 48-weeks, 58 percent (62 of 107 patients) taking LEXIVA/r BID achieved viral loads (VL) below 400 copies/mL, and 46 percent (49) had VL below 50 copies/mL. Of 103 patients who took LPV/r BID, 61 percent (63) achieved VL below 400 copies/mL and 50 percent (52) had VL below 50 copies/mL.

At baseline, patients in both treatment arms had similar viral loads, CD4 cell counts, and PI-associated resistance mutations. Prior NRTI experience and the presence of RT-associated mutations, however, were higher at baseline in patients who subsequently were randomized to the study arm that included LEXIVA/r compared to the group assigned to the study arm containing LPV/r. There was a higher incidence of NRTI mutations in the LEXIVA/r BID group (mean 1.7) compared to the group taking LPV/r BID (1.4). This was primarily due to a higher number of subjects harboring virus with three or more thymidine analogue mutations (TAMS) in the LEXIVA/r BID group (38 percent), compared to 24 percent in the group taking LPV/r BID.

"There was no difference between the LEXIVA/r BID and lopinavir/r BID study arms in the proportion of patients with virologic failure with 29 percent versus 27 percent respectively," said Edwin DeJesus, M.D., Infectious Disease Consultants, Altamonte Springs, FL.

Mutations Present at Baseline
The most common protease-associated resistance mutations seen at baseline among the 210 patients included in the study were:

- L90M in 63 patients (30 percent)
- M46I/L in 48 patients (23 percent)
- D30N in 45 patients (21 percent)

"There was no significant difference between the two study arms in the virologic responses of patients who had these mutations present at baseline," said Rob Elston, GSK scientist and study presenter.

Viral suppression in the presence of L90M was achieved in 16 of 31 patients (52 percent) taking LEXIVA/r, and in 17 of 28 patients (61 percent) taking LPV/r. Among patients with M46I/L mutations, 11 of 22 (50 percent) taking LEXIVA/r and 12 of 24 (50 percent) taking LPV/r responded to treatment, while 21 of 22 patients (95 percent) with D30N mutations responded in the arm containing LEXIVA/r compared to 17 of 18 (94 percent) in the arm containing LPV/r.

Varying degrees of cross-resistance among HIV-1 protease inhibitors have been observed. Because the potential for HIV cross-resistance among protease inhibitors has not been fully explored, it is unknown what effect therapy with LEXIVA will have

on the activity of subsequently administered protease inhibitors. Clinical relevance of resistance data is currently being evaluated.

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 is contraindicated with ergot derivatives, cisapride, pimozide, midazolam, and triazolam. If LEXIVA is coadministered with ritonavir, flecainide and propafenone are also contraindicated. Treatment with LEXIVA and ritonavir has resulted in the increase in concentration of triglycerides. 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.

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.

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.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

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