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48-Week Efficacy Comparison of Lexiva/Ritonavir QD vs. Nelfinavir BID in Therapy-Naive HIV+ Patients: Results Published in AIDS

Research Triangle Park, NC, July 8, 2004 -- The protease inhibitor (PI) LEXIVA(R) (fosamprenavir calcium) dosed with ritonavir (LEXIVA/r) once-daily (QD) as part of a first-line ART regimen provided antiviral suppression that was comparable in this single study to the PI nelfinavir (NFV) dosed twice-daily (BID), according to 48-week data from the SOLO trial published in the journal AIDS. Both regimens were generally well-tolerated, according to the study's authors. LEXIVA (formerly GW433908, or 908), the first PI to combine flexible dosing (QD or BID) in PI-naive patients with no food or water restrictions, was approved by the U.S. Food and Drug Adminstration in October 2003. Co-discovered by GlaxoSmithKline (GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX), 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.

SOLO, an international open-label, multi-center study, evaluated the safety and efficacy of LEXIVA/r QD versus NFV BID, in 649 therapy-naive patients with HIV infection. Patients were randomized to take either two 700mg LEXIVA tablets plus two 100mg ritonavir capsules QD (four pills daily) with no food or water restrictions, or five 250mg nelfinavir tablets BID (10 pills daily) with a meal. All patients also received the nucleoside reverse transcriptase inhibitors abacavir (ABC) and lamivudine (3TC) BID.

"In clinical trials, LEXIVA has been shown to be an effective and well-tolerated PI. LEXIVA also offers flexible dosing regimens, with a low pill burden and options for once- or twice-daily dosing in PI-naive patients. LEXIVA underscores GSK's commitment to provide state-of-the-art antiretroviral therapies for patients," said Doug Manion, M.D., vice president of HIV clinical development and medical affairs at GSK.

In the analysis of data from the SOLO trial reported in AIDS, 69 percent of patients taking LEXIVA/r QD and 68 percent taking NFV BID had viral levels below 400 copies/mL at 48 weeks. Other findings from the 48-week analysis:

- 55 percent of patients taking LEXIVA/r QD and 53 percent taking NFV BID achieved viral loads <50 copies/mL.
- Virologic failure occurred in more patients taking NFV BID (17 percent) than in patients taking LEXIVA/r QD (7 percent), but there were more non-virologic failures with LEXIVA/r than with NFV (24 percent versus 15 percent).
- Median CD4+ count increase from baseline to week 48 was 203 cells/mm3 in the group taking LEXIVA/r QD and 207 cells/mm3 in the NFV BID group.
- Both regimens were well-tolerated. Moderate to severe drug-related diarrhea was more common in patients taking NFV BID than those taking LEXIVA/r QD (16 percent versus 9 percent; p=0.008).
- Fasting lipid profiles were similar in both treatment arms.

SOLO enrolled 649 therapy-naive, ethnic- and gender-diverse patients with HIV (median viral RNA levels were 4.8 log10 copies/mL; median CD4+ counts 170/mm3). Twenty percent of patients entered the SOLO trial with CD4+ cell counts below 50 cells/mm3 and 22 percent had a history of CDC Class C events, (i.e., patient had experienced an opportunistic infection). Baseline characteristics were similar between the two groups.

Clinical Trials with LEXIVA
More than 1,200 people - both ART-naive and PI-experienced patients - participated in three Phase III multicenter trials, including SOLO, 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 NRTIs.

LEXIVA is approved for dosing in therapy-naive patients in one of three ways: 1) two 700mg tablets BID; 2) two 700mg tablets in combination with two 100mg ritonavir capsules QD; or 3) one 700mg tablet in combination with one 100mg ritonavir capsule BID. For PI-experienced patients, the recommended dose is one 700mg tablet BID in combination with one 100mg capsule of ritonavir BID.

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. 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.

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