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Phase III, 48-Week NEAT Study Results Comparing LEXIVA(TM) to Nelfinavir Published in the Journal of Acquired Immune Deficiency Syndrome (JAIDS)

Cambridge, MA and Research Triangle Park, NC, January 20, 2004 -- The final 48-week results from the NEAT trial, an open-label, multi-center study evaluating the safety and efficacy of LEXIVA(TM) (fosamprenavir calcium), the protease inhibitor (PI) formerly known as GW433908 (908), in antiretroviral therapy-naive HIV+ patients versus nelfinavir (NFV/Viracept") have just been published in the January issue of The Journal of Acquired Immune Deficiency Syndrome (JAIDS). Both protease inhibitors were administered in combination with abacavir and lamivudine. In the trial, 66 percent of 166 HIV+ patients (n=109) achieved a viral load (vRNA) <400 copies/mL with LEXIVA, compared to 51 percent of 83 patients (n=42) taking nelfinavir. Researchers stated that LEXIVA "was generally well-tolerated with the convenience of no food or fluid restrictions."

These results come from the final analysis of 48-week data from the NEAT study in which patients were randomized to receive either 1400mg of LEXIVA (2 tablets) twice daily (BID) or 1250mg of nelfinavir (5 tablets) BID. LEXIVA was taken without food or fluid restrictions. Both groups took these medications in combination with 300mg BID of abacavir (ABC) and 150mg BID of lamivudine (3TC). ABC and 3TC are nucleoside analogue reverse transcriptase inhibitors (NRTIs).

"These 48-week data on the safety and efficacy of LEXIVA in a diverse treatment-naive patient population demonstrate that LEXIVA is a promising new addition to current therapy options for individuals infected with HIV," said Doug Manion, M.D., vice president of clinical development at GSK.

LEXIVA was approved by the Food and Drug Administration (FDA) in October 2003 and 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/ritonavir (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.

Efficacy Results from NEAT
"At 48 weeks, 66 percent of 166 HIV-positive patients taking LEXIVA achieved viral load <400 copies/mL, compared to 51 percent of 83 patients taking nelfinavir. More subjects in the NFV group, 28 percent, were considered virologic failures compared to 14 percent of those subjects receiving LEXIVA," said Jeffrey P. Nadler, M.D., University of South Florida College of Medicine, Tampa, a NEAT trial investigator. Further, 55 percent (n=92) of patients in the arm containing LEXIVA achieved a viral load <50 copies/mL, compared to 41 percent (n=34) of patients taking nelfinavir.

Among the approximately 50 percent of patients with high viral loads (>100,000 copies/mL), 67 percent of those taking LEXIVA achieved vRNA <400 copies/mL and 55 percent achieved vRNA <50 copies/mL, versus 35 percent and 24 percent, respectively, among patients taking nelfinavir, according to Dr. Nadler. Among patients with baseline vRNA <100,000 copies/mL, 65 percent in the arm containing LEXIVA achieved an undetectable viral load (<400 copies/mL), compared to 63 percent in the nelfinavir arm. During the 48 weeks of study, the median change from baseline in CD4+ cell counts was 201 cells/mm3 in the group taking LEXIVA and 216 cells/mm3 in the nelfinavir group.

Safety Results from NEAT
The only grade 2-4 drug-related AE that was significantly different was diarrhea, which was significantly more prevalent in patients receiving nelfinavir (18 percent) than in patients receiving LEXIVA (5 percent). The overall incidence of other drug-related Grade 2-4 AEs was comparable between the two groups. The other most common drug-related AEs with LEXIVA were rash (7 percent) and nausea (5 percent); with NFV they were nausea (4 percent) and vomiting (4 percent).

No subject in the group taking LEXIVA experienced a Grade 3-4 elevation in triglycerides or total cholesterol. No patients in the NFV group experienced Grade 3-4 elevations in total cholesterol, and 1 percent of the NFV patients experienced a Grade 3-4 elevation in triglycerides.

NEAT Study Demographics
The study population included:

- A large proportion of patients with advanced HIV disease -- Nearly 50 percent had viral loads greater than 100,000 copies at baseline, and approximately 50 percent had CD4+ counts below 200 cells/mm3, a criterion that meets the definition of AIDS established by the Centers for Disease Control and Prevention (CDC). Eighteen percent of patients had CD4+ counts <50 cells/mm3 at baseline.
- Gender diversity -- with females representing 31 percent of the patient population.
- Ethnic diversity -- including a high proportion of Hispanic patients (44 percent) and patients of African descent (32 percent).

Fosamprenavir is the calcium phosphate ester pro-drug of amprenavir. For the protease inhibitor component of the study, patients in the group taking LEXIVA took 2 pills BID compared to 5 pills BID in the nelfinavir group. Two dosing frequencies have been studied for LEXIVA, both without food or fluid restrictions: twice a day (BID with or without ritonavir) and once a day (QD) in combination with low dose ritonavir. Once-daily administration of LEXIVA plus ritonavir is not recommended for PI-experienced patients.

Important Safety Information about LEXIVA
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.

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 new HIV protease inhibitor, Lexiva(TM), 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 31, 2003.

Vertex Contacts:
Lynne H. Brum, VP, Corporate Communications and Financial Planning, (617) 444-6614
Michael Partridge, Director, Corporate Communications, (617) 444-6108

GlaxoSmithKline Contact:
Mary Faye Dark, (919) 483-2839