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Studies of Sustained Efficacy/Tolerability of LEXIVA After 96 Weeks of Treatment Presented at IAC

Bangkok, July 13, 2004 -- The protease inhibitor (PI) LEXIVA(R) (fosamprenavir calcium, formerly GW433908, or 908) in combination with abacavir and lamivudine demonstrated sustained efficacy and safety after long-term treatment (96 weeks), according to studies of treatment results in therapy-naive patients, approximately 50 percent of whom had baseline CD4 cell counts less than 200 cells/mm3. APV30005 was a rollover trial for patients enrolled in SOLO and NEAT, two Phase III clinical trials that were pivotal to the October 2003 FDA approval of LEXIVA. The data were presented here today at the International AIDS Conference (IAC). LEXIVA was co-discovered by GlaxoSmithKline (GSK) and Vertex Pharmaceuticals (Nasdaq: VRTX).

This study reported results of long-term treatment with LEXIVA dosed with ritonavir (LEXIVA/r) once a day (QD) in patients from SOLO and outcomes from patients in NEAT, who took LEXIVA without ritonavir twice a day (BID). LEXIVA was given in combination with abacavir and lamivudine. In this analysis, viral suppression and immunologic improvements were sustained through 96 weeks of treatment with LEXIVA and LEXIVA/r. At the time this preliminary analysis was performed, approximately half the patients (175 out of 322) had reached 96 weeks. This study is on-going. LEXIVA and LEXIVA/r were well-tolerated, with < two percent of the patients discontinuing due to adverse events.

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.

"We are encouraged by the preliminary analyses of 96-week data that suggest the potency and safety demonstrated by LEXIVA at 48 weeks may be sustained by long-term treatment in naive patients," said Doug Manion, M.D., vice president of HIV Medicines Development Center at GSK.

LEXIVA/r QD (poster # 4507)
A total of 210 patients (median baseline viral load 4.82 log10 copies/mL and median CD4 cell count of 168 cells/mm3) taking LEXIVA/r QD with abacavir and lamivudine who completed SOLO subsequently enrolled in the follow-up study, APV30005. Of these patients, 115 completed 96 weeks of therapy before the deadline for data collection, and were included in the interim analysis presented at IAC. Of 113 patients for whom lab data were available, 109 (96 percent) had VL below 400 copies/mL and 97 (86 percent) had VL below 50 copies/mL at 96 weeks. From baseline to week 96, median CD4 cell counts increased from 168 to 461 cells/mm3 indicating continued immunologic improvement. No selection of PI-resistant mutations was observed in any patients with virologic failure over the 96 weeks.

"In this analysis, long-term treatment with LEXIVA/r QD resulted in sustained virologic suppression, continued immunologic improvements and no selection of PI-resistance up to 96 weeks," said Joseph C. Gathe, Jr., M.D., F.A.C.P., clinical instructor, Department of Internal Medicine, Baylor College of Medicine, Houston, Texas.

The most common moderate to severe drug-related adverse events over the 96-week study period with LEXIVA/r QD were diarrhea (9 percent of patients) and nausea (7 percent), most of which occurred before patients completed the 48-week SOLO trial. No new cases of diarrhea and only one new case of drug-related nausea were reported in APV30005. Of 19 patients (9 percent) who discontinued treatment between 48 and 96 weeks, 4 (2 percent) discontinued due to an adverse event. Fasting HDL cholesterol levels continued to increase from baseline to week 96 (mean change of 12 mg/dL). Mean triglyceride and total cholesterol values increased from baseline to week 48, they remained stable from week 48 to week 96.

LEXIVA BID (poster # 4506)
APV30005 enrolled 112 patients (median baseline viral load of 4.82 log10 copies/mL and 216 CD4 cells/mm3) from the NEAT trial who had completed 48 weeks of treatment with LEXIVA BID with abacavir and lamivudine. A total of 60 patients completed 96 weeks. Fifty-four of the 60 (90 percent) had viral load (VL) below 400 copies/mL and 51 (85 percent) had VL below 50 copies/mL at 96 weeks. The median increase in CD4 cell counts was 205 cells/mm3 at 48 weeks, rising to a total median increase of 255 cells/mm3 over 96 weeks of treatment. Fasting HDL cholesterol levels continued to increase from baseline to week 96 (mean change of 11 mg/dL), with no significant increase in the TC/ HDL-C ratio. Although increases were observed in mean triglyceride values during the study, the mean values returned to baseline in those patients who had completed 96 weeks of the study as of the data cut-off (or at the time of data analyses).

"Over a long-term course of treatment, LEXIVA sustained its potency in suppressing HIV, was well-tolerated, and no new safety concerns were observed over 96 weeks of treatment," said Jeffrey P. Nadler, M.D., University of South Florida College of Medicine, Tampa, Fla.

The most common moderate to severe drug-related adverse events were diarrhea (8 percent), nausea (8 percent) and rash (5 percent). The discontinuation rate was low (6 percent) and no patients discontinued the regimen because of adverse events. Selection of PI-associated resistance mutations was observed in five patients with viral loads above 1000 copies/mL.

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

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