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## **New Pharmacokinetic Data on Co-Administration of the PI LEXIVA/r With the NRTI Tenofovir**

**Quebec City, April 29, 2005** --Today new study results announced by GlaxoSmithKline showed the pharmacokinetics (PK) of the HIV protease inhibitor (PI) LEXIVA(R) (fosamprenavir calcium) dosed in combination with either 100mg or 200mg of the PI ritonavir (RTV) (LEXIVA/r) was not affected when LEXIVA/r was co-administered once daily (QD) with the nucleotide reverse transcriptase inhibitor Viread (tenofovir disoproxil fumarate) (TDF). There also were no significant safety findings when combining LEXIVA/r with TDF in the 35 healthy male volunteers studied. The data were presented at the 6th International Workshop on Clinical Pharmacology of HIV Therapy.

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

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 RTV is not recommended for PI-experienced patients.

"These data complement findings from a clinical study of LEXIVA/r in protease inhibitor-experienced patients wherein plasma amprenavir trough concentrations were similar for subjects receiving tenofovir as compared to subjects not receiving tenofovir," said Doug Manion, M.D., vice president for HIV Clinical Research for the Infectious Diseases Medicines Development Center (MDC), GlaxoSmithKline.

This study was a prospective, crossover study of 35 male volunteers. All subjects took LEXIVA/r in combination with TDF 300mg once daily in a fasted state. One cohort took LEXIVA 1400mg/ritonavir 200mg once daily and the other cohort took LEXIVA 1400mg/ritonavir 100mg once daily. After 14 days, a 24-hour PK profile was measured.

### **Specific results:**

No relevant effects of TDF on plasma amprenavir (APV) PK were demonstrated when once daily TDF 300mg was given in combination with once daily LEXIVA/r 1400/100 or 1400/200.

There were no grade III-IV adverse events in any study group.

### **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. 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. The most common adverse events seen in clinical trials with LEXIVA were diarrhea, nausea, vomiting, headache and rash.

### **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 companies. Vertex's product pipeline is principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the HIV protease inhibitor, LEXIVA with GlaxoSmithKline.

LEXIVA 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 16, 2005.

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