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## **GlaxoSmithKline and Vertex Pharmaceuticals Announce Preliminary 48-Week Results from Head-to-Head Clinical Study of HIV Protease Inhibitors Lexiva (Telzir) and Kaletra in Treatment-naive Patients with HIV**

**Research Triangle Park, NC, and Cambridge, MA, May 16, 2006--** GlaxoSmithKline (GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced preliminary 48-week results from a head-to-head clinical study that indicated that Lexiva (Telzir; fosamprenavir calcium) 700 mg plus ritonavir 100 mg given twice daily was comparable (non-inferior) to Kaletra (lopinavir/ritonavir fixed-dose combination) given twice daily in treatment-naive HIV patients. All patients in the study also received a once-daily fixed-dose combination of abacavir 600 mg and lamivudine 300 mg as the backbone of antiretroviral therapy.

In the study, which enrolled 887 patients, 73 percent of patients receiving Lexiva/ritonavir maintained suppression of viral replication (less than 400 copies/mL plasma HIV RNA) after 48 weeks of dosing, compared with 71 percent of patients receiving Kaletra (Intent-to-Treat Analysis). The results will be submitted to the FDA and other health regulatory authorities when the final analysis is concluded.

Lexiva/ritonavir was compared to Kaletra in this study due to Kaletra's position as the preferred HIV protease inhibitor in HIV treatment guidelines developed by the United States Department of Health and Human Services (DHHS) and the International AIDS Society (IAS). Based on these results from this study, researchers have concluded that Lexiva appears to be comparable to Kaletra and has met the primary endpoints of this non-inferiority trial.

GSK will present results from the study at a medical conference in 2006. Lexiva was co-discovered by Vertex and GlaxoSmithKline.

### **KLEAN Study Design and Results**

The results announced today are from the KLEAN study, a randomized, open-label study of the safety and efficacy of Lexiva, dosed as 700 mg twice daily, in combination with 100 mg ritonavir twice daily, versus Kaletra, dosed as 400 mg in a fixed-dose combination with 100 mg ritonavir twice-daily, in 887 treatment-naive HIV infected adults for 48 weeks. All patients in the study received concomitant treatment with a once-daily fixed-dose combination of 600 mg abacavir and 300 mg lamivudine.

Preliminary results indicated that 73 percent of patients receiving Lexiva plus ritonavir in combination therapy maintained suppression of viral replication (less than 400 copies/mL plasma HIV RNA) after 48 weeks of dosing, compared with 71 percent of patients receiving Kaletra in combination therapy (95 percent CI, -3.26,5.47). The treatments were found to be non-inferior. These preliminary analyses therefore suggest that Lexiva has comparable activity to Kaletra based on the proportion of patients who have less than 400 copies/mL HIV RNA at 48 weeks of dosing.

Both regimens were generally well-tolerated. A total of 6 percent of subjects withdrew due to adverse events. Adverse events in this study were consistent with those described in product information for Lexiva and Kaletra.

### **Important Prescribing and Safety Information**

LEXIVA is indicated in combination with other antiretroviral agents for the treatment of HIV infection in adults. The PI-experienced patient study was not large enough to reach a definitive conclusion that LEXIVA/ritonavir and lopinavir/ritonavir are clinically equivalent. Once-daily administration of LEXIVA/ritonavir is not recommended for PI-experienced patients. LEXIVA does not cure HIV or prevent passing HIV to others.

You should not take LEXIVA if you have had an allergic reaction to LEXIVA or AGENERASE(R) (amprenavir). High blood sugar, diabetes or worsening of diabetes, and bleeding in hemophiliacs have occurred in some patients taking protease inhibitors. When you start taking HIV medicines, your immune system may get stronger and could begin to fight infections that have been hidden in your body, such as pneumonia, herpes virus, or tuberculosis. If you have new symptoms after starting your HIV medicines, be sure to tell your doctor. Changes in body fat may occur in some patients taking antiretroviral therapy. The cause and long-term health effects of these conditions are not known at this time. Skin rashes can occur in patients taking LEXIVA. Rarely, rashes were severe or life threatening. Opportunistic infections can develop when you have HIV and your immune system is weak. It is very important that you see your healthcare provider regularly while you are taking LEXIVA to discuss any side effects or concerns. Most common side effects in clinical studies were diarrhea, headache, nausea, rash, and vomiting. In

most cases, these side effects did not cause people to stop taking their medicine.

For full prescribing information for LEXIVA, please visit [www.treathiv.com](http://www.treathiv.com)

**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 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.

**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, among other things, the risks that full analysis of the data, including an ongoing detailed safety analysis, or further testing, will not reflect the preliminary results reported in this press release, or support any or all of the conclusions provided in this press release; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.  
Kaletra is a registered trademark of Abbott Laboratories.

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