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GSK and Vertex Pharmaceuticals Announce Presentation of Data Supporting Development of Investigational HIV Protease Inhibitor Brecanavir

- Positive Data Presented at 45th Annual ICAAC -

Cambridge, MA, December 16, 2005 - GlaxoSmithKline (GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) presented positive results today from a study evaluating the safety, tolerability and antiviral activity of the investigational HIV-1 protease inhibitor (PI), brecanavir* (formerly known as GW640385 or VX-385)1. These data were presented at the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) held in Washington DC. Interim findings following 24 weeks of dosing demonstrated potent antiviral activity for brecanavir in both PI-sensitive and PI-resistant HIV-infected adults.

"These results support the ongoing development program for brecanavir, which is anticipated to enter Phase III development in 2006," said Lynn Marks, MD, Senior Vice President of the Infectious Disease Medicines Development Centre at GSK. "If approved, brecanavir may be useful in treating patients infected with strains of HIV that have become resistant to multiple protease inhibitors, and its clinical advancement underscores GSK's commitment to developing new anti-HIV drugs."

Clinical Data on Brecanavir

Brecanavir is an HIV protease inhibitor in Phase IIb clinical development. Brecanavir has received fast track designation from the U.S. Food and Drug Administration and is being developed by GSK as part of a collaboration with Vertex Pharmaceuticals.

Data presented were from a planned, 24-week analysis of an open-label study (HPR10006) of 48 weeks' duration evaluating the safety, tolerability, antiviral activity and pharmacokinetics of ritonavir-boosted brecanavir. Thirty-one HIV-1 infected adults received 300mg of brecanavir twice-daily boosted with 100mg of ritonavir in combination with two nucleoside reverse transcriptase inhibitors based on patient medical history and viral genotype.

Out of 31 patients, 81 percent had plasma HIV-1 RNA below the level of detection of standard assays (<400 copies/mL of blood) at Week 24 (based on an intent-to-treat, missing or discontinuation equals failure analysis), and 77 percent had viral load below the level of detection of ultrasensitive assays (<50 copies/mL). Patients with PI-sensitive and highly PI-resistant virus had similar response rates. Improvements in immunologic status were observed, with a median increase in CD4+ cell count of 84 cells/mm3.

"These early data are encouraging and support the further development of brecanavir in clinical trials in both antiretroviral treatment-naïve and experienced patients," commented lead investigator Douglas Ward, MD, FACP of the Dupont Circle Physicians Group. "Because many HIV-infected patients undergoing treatment develop viral resistance to those medicines already available, a critical need for new antiretrovirals remains."

A safety assessment showed that brecanavir was well-tolerated with few Grade 2-4 drug-related adverse events and no serious adverse events. Most adverse events were reported as mild and did not require treatment modification or discontinuation. Clinically relevant changes in laboratory assessments were also infrequent.

About HIV Protease

Once inside a human immune cell, HIV uses enzymes within that cell to make copies of itself. Protease is one such enzyme involved in HIV replication. HIV protease inhibitors block the HIV protease enzyme, yielding copies of HIV that cannot infect new cells.

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 Safe Harbor Statement

This press release may contain forward-looking statements, including that (i) it is anticipated brecanavir will enter Phase III development in 2006; and (ii) brecanavir may be useful in treating patients infected with resistant HIV strains. 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 the actual results of studies to vary materially, including those risks and uncertainties 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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1D. Ward, et al. Preliminary Antiviral Activity and Safety of 640385/Ritonavir in HIV-infected Patients (Study HPR10006); an 8-Week Interim Analysis. 45th Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington DC, Dec 2005.

*The generic name is USAN approved only.