



February 7, 2006

## **Vertex Successfully Completes Key Studies with VX-950 to Prepare for Next Steps in Clinical Program**

### **-Plasma HCV RNA levels are less than 10 IU/mL in 12 of 12 patients after 28 days of dosing with VX-950/peg-IFN/RBV in Phase II study-**

**Cambridge, MA, February 7, 2006-** Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that it has completed dosing with VX-950 in a Phase II, 28-day clinical study in hepatitis C virus (HCV) infected patients. In addition, the Company announced that it has completed three-month animal toxicology studies that will support clinical studies of VX-950 of up to three months duration. Initiation of additional Phase II clinical studies in the U.S. in patients with HCV is planned following required Food and Drug Administration (FDA) review of these latest non-clinical and clinical results, and FDA review of a proposed clinical study protocol. This information will be submitted to the FDA within the first quarter of 2006.

### **Clinical Study Design and Results**

The 28-day, Phase II clinical study enrolled 12 treatment-naïve patients with genotype 1 HCV. Patients received VX-950 in a tablet formulation at a dose of 750 mg every eight hours (q8h) for 28 days in combination with standard doses of pegylated interferon alfa-2a (Pegasys®; peg-IFN) and ribavirin (Copegus®; RBV). At the end of 28 days, patients completed dosing with VX-950 and per study protocol were required to continue treatment with peg-IFN and RBV. This 28-day Phase II study was not designed to evaluate sustained viral responses (SVR) in patients receiving VX-950.

There were no treatment discontinuations and no serious adverse events reported. A detailed safety analysis is ongoing.

For patients entering the study, the distribution of baseline plasma HCV RNA values was typical for a treatment-naïve patient population. At the end of week 1 (day 8 of VX-950 dosing), plasma HCV RNA was below the limit of quantitation (30 IU/mL; Roche Taqman® assay) in 6 of the 12 patients; and undetectable (less than 10 IU/mL; Roche Taqman® assay) in 2 of 12 patients. Preliminary HCV RNA results in patients for weeks 2-4 are as follows:

- At the end of week 2, plasma HCV RNA was below the limit of quantitation (30 IU/mL) in 11 of the 12 patients; and undetectable (less than 10 IU/mL) in 3 of 12 patients.
- At the end of week 3, plasma HCV RNA was below the limit of quantitation (30 IU/mL) in 12 of the 12 patients; and undetectable (less than 10 IU/mL) in 9 of 12 patients.
- At the end of VX-950 dosing (end of week 4; day 28), plasma HCV RNA was undetectable (less than 10 IU/mL) in all 12 patients.
- No patients showed evidence of viral breakthrough while on treatment.

The Phase II study reported today is the third in a series of clinical trials of VX-950 in patients with HCV designed to evaluate safety, pharmacokinetics and antiviral activity, in order to guide the design of larger, longer duration Phase II studies. The Company plans to present the full data set from the 28-day Phase II study at a medical conference later this year.

### **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, including statements that (i) Vertex will submit data from the toxicology and clinical studies to the FDA within the first quarter; (ii) the Company's three month animal toxicology data support clinical studies of VX-950 of up to three months duration; and (iii) additional Phase II clinical studies in the U.S. are planned following FDA review of data from Vertex studies and the Company's proposed clinical study protocols. 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 interim results reported in this press release, or support any or all of the conclusions provided in this press release; the FDA will not agree to a clinical trial designed to determine SVR after three months of combination treatment; clinical trials for VX-950 may not proceed as planned due to technical, scientific, or patient enrollment issues; expected regulatory filings or clinical trial starts may not occur or may be delayed due to adverse clinical or non-clinical trial developments or FDA action, any one or more of which events could delay the start of Phase III clinical trials and planned filings for regulatory approval; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2005.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies, and Pegasys is a registered trademark of Hoffman-La Roche Inc.

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[Back to the 2006-2005 Press Releases](#)