

December 8, 2005

# FDA Grants Fast Track Designation to Vertex's Investigational Oral Hepatitis C Virus Protease Inhibitor VX-950

**Cambridge, MA, December 8, 2005** - Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to VX-950, an investigational oral hepatitis C virus (HCV) protease inhibitor for the treatment of HCV infection. The FDA granted Fast Track designation to VX-950 for the following reasons:

- Chronic hepatitis C virus infection is a serious and life-threatening disease.
- VX-950 has the potential to shorten the duration of therapy compared to the standard of care, which may result in improved sustained virologic response rates and a more favorable adverse event profile.
- Vertex is currently conducting a clinical development program to assess whether VX-950 will address these unmet medical needs in HCV therapy.

Under the FDA Modernization Act of 1997, Fast Track designation indicates that the FDA will facilitate the development and may expedite the review of a drug if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address an unmet medical need for such a condition.

## **VX-950 Clinical Status**

Earlier in 2005, Vertex concluded a 14-day, Phase Ib study of VX-950 that showed a rapid and dramatic reduction in HCV RNA in HCV patients when VX-950 was administered as a single agent. Overall in the Phase Ib study, adverse events observed in patients receiving VX-950 that were considered possibly related to the drug were mild, and generally similar in frequency to events in the placebo group. The most common adverse events reported in both placebo and VX-950 patients were headache, frequent urination and gastrointestinal symptoms. Based on these encouraging Phase Ib clinical results, Vertex recently initiated two additional clinical studies with VX-950. In October 2005, Vertex initiated in Europe a 20-patient Phase Ib study of VX-950 dosed in combination with pegylated interferon. In December 2005, Vertex initiated in the United States the first Phase II study of VX-950, which will evaluate the safety, tolerability and pharmacodynamics of VX-950 when dosed with pegylated interferon and ribavirin. Vertex expects to obtain results from both these Phase Ib and Phase II studies of VX-950 in early 2006. Vertex also expects to initiate multiple additional Phase II studies in the United States in 2006, including a three-month study in more than 200 treatment-naive patients.

# **About Hepatitis C**

Hepatitis C is a liver disease caused by the hepatitis C virus, which is found in the blood of people with the disease. HCV, a serious public health concern affecting 3.4 million individuals in the United States, is spread through direct contact with the blood of infected people. Though many people with hepatitis C may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Hepatitis C significantly increases a person's risk for developing long-term infection, chronic liver disease, cirrhosis or death.

#### **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.

#### **Safe Harbor Statement**

This press release may contain forward-looking statements, including statements that (i) VX-950 may shorten the duration of HCV therapy compared to the standard of care; (ii) VX-950 may improve sustained virologic response rates in HCV patients; (iii) VX-950 may have a more favorable side effect profile than the current standard of care therapy; (iv) VX-950 will address unmet medical needs in HCV therapy; (v) Vertex will advance VX-950 in clinical development; and (vi) Vertex will initiate multiple Phase II clinical studies of VX-950 in 2006, including a three-month study in more than 200 treatment-naive patients. 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 clinical trials for VX-950 may not proceed as planned due to technical, scientific, or patient enrollment issues, or negotiations with regulatory authorities over trial design or other matters, that the scale and scope of future clinical and nonclinical studies may change and will be determined in significant part by data collected in ongoing and future trials, that further clinical studies of VX-950 may not reflect the results obtained in early clinical and nonclinical studies, that ongoing nonclinical studies, including toxicology studies, will yield currently unanticipated negative outcomes, that results from the Company's clinical trials commenced during 2006 will be insufficient to support a Phase III program without additional trials and consequent delay in the timetable for potential 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.

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