



December 13, 2006

## Pharmaceuticals Announces Results of First Interim Safety and Antiviral Analysis of the PROVE 1 Clinical Trial of Investigational HCV Protease Inhibitor Telaprevir (VX-950)

**Cambridge, MA, December 13, 2006** – Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced results from a planned interim safety analysis from PROVE 1, an ongoing Phase 2b clinical trial of the investigational hepatitis C virus (HCV) protease inhibitor telaprevir (VX-950):

- In the telaprevir dosing arms, the incidence of treatment discontinuations due to adverse events was 9% and the incidence of serious adverse events was 3%.
- At week 12, 65 of the 74 patients (88%) for whom data was available in the telaprevir groups demonstrated undetectable HCV RNA (less than 10 IU/mL; Roche Taqman).
- Vertex earned a \$15 million milestone payment from Janssen Pharmaceutica NV, based on these results.

“Chronic hepatitis C infection is a major public health problem, and Vertex’s goal is to increase the success rate of hepatitis C treatment with short-duration therapy,” said Joshua Boger, Ph.D., President and Chief Executive Officer of Vertex. “Evaluation of telaprevir’s safety and antiviral activity in multiple large clinical trials is Vertex’s top clinical priority in the year ahead. This interim analysis of PROVE 1 is an important step forward in the telaprevir clinical development program, as it strongly supports the initiation and conduct of large clinical trials designed to evaluate the safety and antiviral activity of telaprevir.”

### Interim Safety and Antiviral Results

In accordance with the PROVE 1 study design, an interim safety and antiviral activity analysis has been conducted, and the data have been reviewed by the independent data monitoring committee overseeing the trial. A total of 250 patients were enrolled and in addition to Peg-interferon alfa-2a (peg-IFN) + ribavirin (RBV) received at least one dose of telaprevir or placebo in the study. In the data reported, patients in all three telaprevir containing groups were pooled together (n=175) and the results were compared to the results in the control arm of peg-IFN + RBV and placebo (n=75). At the time of the data cut-off for the safety analysis, approximately 100 patients had completed 12 weeks on-study and more than 200 patients had completed 8 weeks.

The most common adverse events were similar in type between the two groups and were characteristic of the known side effects of interferon and ribavirin. Of these, the adverse events that were more commonly reported in the telaprevir groups included gastrointestinal disorders and rash. In the telaprevir groups, as of the cut-off date, 9% of patients had discontinued treatment due to adverse events, compared to 3% of patients in the control arm. The difference between the two groups is due to the greater number of discontinuations due to rash, gastrointestinal disorders, and anemia in the telaprevir arms compared to the control arm. Three percent (3%) of patients in the telaprevir arms discontinued due to rash, the most common adverse event leading to treatment discontinuation in the study. Serious adverse events were noted in 3% of patients in the telaprevir groups and 1% of patients in the control group.

The table below summarizes available HCV RNA results at week 12:

Treatment assignment	Patients who had undetectable HCV RNA (less than 10 IU/mL) at week 12
VX-950+ peg-IFN +RBV	65 of 74 (88%)
Placebo+peg-IFN +RBV	17 of 33 (52%)

Of the 74 patients in the telaprevir groups for whom data were available at the end of 12 weeks, 65 (88%) demonstrated undetectable HCV RNA (less than 10 IU/mL; Roche Taqman), compared to 17 of 33 (52%) of patients in the control arm. Vertex expects that further results for the PROVE 1 clinical trial will be presented at a medical forum in 2007.

### About the PROVE 1 Study

PROVE 1 is a four-arm, double-blind, placebo-controlled Phase 2b clinical trial of telaprevir (VX-950) in treatment naive patients with genotype 1 HCV infection. The protocol placed no restriction on patient entry into the trial based on weight, race/ethnicity or baseline viral load. In the trial, telaprevir was dosed in combination with pegylated interferon-2a (peg-IFN-2a) and ribavirin (RBV). The primary objective of PROVE 1 is to assess the proportion of patients in each study arm who achieve sustained viral response (SVR), defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan assay) HCV RNA 24 weeks after the completion of dosing. The study was fully enrolled in September 2006 and is ongoing at approximately 35 centers in the U.S. All subjects will have completed telaprevir dosing by the third week of December 2006. A full description of the PROVE 1 trial design can be found in Vertex's May 23, 2006 press release.

### **About Telaprevir (VX-950)**

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is one of the most advanced investigational agents in development that specifically targets HCV. Vertex is conducting a global Phase 2b clinical development program for telaprevir consisting of three large clinical trials that are expected to enroll approximately 1000 patients with HCV at clinical centers in the United States and Europe. The U.S.-based PROVE 1 trial is fully enrolled and ongoing. The PROVE 2 study is underway in Europe and is expected to complete enrollment with approximately 320 patients within the next few weeks. Also in the next few weeks, Vertex expects to initiate PROVE 3, a clinical trial of telaprevir that will enroll more than 400 treatment-experienced patients. In clinical trials, telaprevir is being dosed as 750 mg every eight hours in combination with pegylated interferon alfa-2a (Pegasys<sup>®</sup>), both with and (in the PROVE 2 study) without ribavirin (Copegus<sup>®</sup>).

Vertex retains commercial rights to telaprevir in North America. Vertex, Janssen Pharmaceutica and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East, and other countries. Janssen is funding approximately 50% of development costs, in addition to paying Vertex milestone payments based on successful development and launch of telaprevir in Janssen's territories. Vertex is collaborating with Mitsubishi Pharma to develop and commercialize telaprevir in Japan and certain Far East countries.

### **About Hepatitis C**

Hepatitis C is a liver disease caused by infection with hepatitis C virus (HCV), which is found in the blood of people with the disease. HCV, a serious public health concern affecting 170 million people worldwide, is spread through direct contact with the blood of an infected person. 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 of developing chronic liver disease, cirrhosis, liver cancer and 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 focused on viral diseases, inflammation, autoimmune diseases, cancer, pain and bacterial infection. Vertex co-discovered 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) data from the interim safety analysis support initiation of further clinical studies by Vertex, including the PROVE 3 study and other large clinical trials designed to evaluate the safety and antiviral activity of telaprevir; (ii) the Company's goal is to increase the success rate of hepatitis C treatment with shorter duration therapy; (iii) the Company's interim results are indicative of final results that may be expected from the PROVE 1 study; (iv) Vertex is conducting a global development program for telaprevir consisting of three large clinical trials that are expected to enroll approximately 1,000 patients; (v) PROVE 2 is expected to complete enrollment with approximately 320 patients within the next few weeks; and (vi) also in the next few weeks, Vertex expects to initiate the PROVE 3 clinical trial that will enroll more than 400 treatment-experienced 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 the actual results of studies to vary materially. Those risks and uncertainties include, among other things, the risk that the results of the interim analysis of safety and clinical activity will not be consistent with the eventual final trial outcomes, that the Company's study objectives for each of its planned studies may not be achieved, that regulatory authorities may not allow the Company's planned trials to proceed as designed, due to varying interpretations of existing and expected data or disagreements over trial design or for other reasons, that enrollment may be more difficult or slower than the Company currently anticipates or that planned studies may not start when planned due to regulatory issues, site startup delays, availability of clinical trial material or other reasons, or other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006. Vertex disclaims any obligation to update the information contained in this press release as new data become available.

### **Vertex Contacts:**

Lynne H. Brum, VP, Strategic Communications (617) 444-6614

Michael Partridge, Director, Corporate Communications, (617) 444-6108

Lora Pike, Manager, Investor Relations, (617) 444-6755  
Zachry Barber, Senior Media Relations Specialist, (617) 444-6470

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