



April 29, 2006

Researchers Report Initial Results for 14-day Phase Ib Study of VX-950, and Pegylated Interferon, Showing Anti-HCV Activity in Combination in Hepatitis C Patients

-New data show that plasma HCV RNA levels were below limit of detection (10 IU/mL) in 8 of 8 patients continued on peg-IFN+RBV for 12 weeks-

Vienna, Austria, April 29, 2006- Data presented at the 41st Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna today show that when VX-950, an investigational oral hepatitis C virus (HCV) protease inhibitor being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX), was dosed with pegylated interferon alfa-2a (Pegasys[®]; peg-IFN), the combination was well-tolerated and achieved a dramatic reduction in plasma viral RNA levels in patients with chronic genotype 1 HCV infection through 14 days of dosing. At day 14, the majority of patients (6 of 8) receiving the combination had HCV RNA levels below the limit of quantitation (30 IU/mL, as measured by the Roche TaqMan[®] assay), and 4 of 8 patients had HCV RNA levels below the limit of detection (10 IU/mL, Roche TaqMan[®]). All patients enrolled in the 14-day study subsequently received follow-on treatment with peg-IFN and ribavirin (RBV). Researchers reported for the first time today that 8 of 8 patients who received VX-950 and peg-IFN in combination for 14 days have no detectable virus in their blood at the end of 12 additional weeks of peg-IFN+RBV dosing. These patients continue to receive peg-IFN+RBV. All patients were offered follow-on peg-IFN+RBV treatment according to clinical practice at the investigator sites.

"In the 14-day study, VX-950 in combination with pegylated interferon produced a very rapid viral response in each of these genotype 1 patients, and no serious adverse events were observed," said Henk W. Reesink, MD, Associate Professor of Medicine at Academic Medical Center in Amsterdam, and a lead investigator for the study. "The continued viral suppression during follow-on therapy points to the robustness of the viral response to VX-950 and pegylated interferon, and is encouraging for the design of future VX-950 studies that seek to evaluate the potential for short-course, curative therapy."

Study Design and Results

The 14-day, randomized, blinded, placebo-controlled Phase Ib study enrolled 20 treatment-naive patients with genotype 1 HCV, the most prevalent and difficult to treat form of HCV infection. Patients were randomized to receive a new tablet formulation of VX-950 at a dose of 750 mg every eight hours (q8h) in combination with a standard dose of peg-IFN (n=8), the same dose of VX-950 administered alone (n=8), or a standard dose of peg-IFN alone (n=4). The median viral load for all patients at study entry was 6.65 log₁₀ IU/mL HCV RNA (approximately 4.4 million IU/mL). In this Phase Ib study, the combination of VX-950 and peg-IFN produced an initial median reduction in plasma HCV RNA of more than 3 log₁₀ in the first two days. Antiviral results for all arms after 14 days of dosing were as follows:

- A median 5.5 log₁₀ reduction in HCV RNA was observed in patients receiving VX-950 and peg-IFN; 6 of 8 patients had viral levels below the limit of quantitation (30 IU/mL) at 14 days, and 4 of 8 also achieved viral levels below the limit of detection (10 IU/mL).
- A median 4.0 log₁₀ reduction in HCV RNA was observed in patients receiving VX-950 alone; 1 of 8 patients had viral levels below the limit of detection (10 IU/mL).
- A median 1.0 log₁₀ reduction in HCV RNA was observed in patients receiving peg-IFN alone; no patients had viral levels below the limit of quantitation (30 IU/mL) at 14 days.
- Following the 14-day Phase Ib study, patients were rolled onto follow-on treatment with peg-IFN and ribavirin.

Safety

A complete safety review has been conducted. All patients completed dosing and no serious adverse events were reported. The most common adverse events among all treatment arms, all of which were mild to moderate in severity, were headache, myalgias, dry skin, diarrhea, nausea, chills and rash. VX-950 did not appear to substantially increase the frequency or severity of these events when added to peg-IFN, and the observed safety profile supports the evaluation of VX-950 in studies of longer duration. All adverse events in the patients receiving VX-950 alone were reported as mild. Typical interferon-related side effects, of mild to moderate severity, were reported in the patients that received peg-IFN along with VX-950 or placebo.

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. The burden of liver disease associated with HCV infection is increasing, and current therapies only provide sustained benefit in about 50% of patients with genotype 1 HCV, the most common strain of the virus. Specifically targeted antiviral therapies for HCV in clinical development have the potential to increase the proportion of patients who can eradicate the virus.

About VX-950

VX-950 is an investigational oral inhibitor of hepatitis C virus protease, an enzyme essential for viral replication, and is one of the most advanced investigational agents that specifically targets HCV. In early 2006, Vertex reported preliminary results from a 28-day, Phase II study of VX-950 dosed in combination with peg-IFN and ribavirin. In this study, 12 of 12 patients had plasma HCV RNA levels below the limit of detection (10 IU/mL) at 28 days. There were no treatment discontinuations and no serious adverse events reported. In clinical studies of up to 14 days duration, the most common adverse events reported, including patients who did not receive VX-950, and regardless of possible relationship to drug, have been headache, frequent urination, gastrointestinal symptoms, myalgias, skin disorders and chills. All of these adverse events have been reported as mild to moderate in severity.

Vertex researchers were the first to solve the three-dimensional crystal structure of HCV protease, and have used structural insights to enable the design of small molecule HCV protease inhibitors, including VX-950.

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. In collaboration with GlaxoSmithKline, Vertex co-promotes the HIV protease inhibitor, Lexiva.

Safe Harbor Statement

This press release may contain forward-looking statements, including a statement that results from the Phase Ib study are encouraging for the design of future VX-950 studies that seek to evaluate the potential for short-course, curative therapy. 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 (i) full analysis of the data, 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; and (ii) clinical trials for VX-950 may not proceed as planned due to technical, scientific, or patient enrollment issues, clinical trial results may not be available when expected, or expected regulatory filings may not occur or may be delayed due to adverse clinical or non-clinical trial developments or unanticipated FDA action; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

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