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Telaprevir-Based PROVE Studies Show Significantly Higher SVR Rates in Treatment-Naive Genotype 1 Hepatitis C Patients in Half the Time of Current Treatments

- High sustained virologic response (SVR) rates of 61% in PROVE 1 and 68% in PROVE 2 with 24-week telaprevir-based treatment regimen -

- Telaprevir first and only investigational HCV protease inhibitor in Phase 3, ADVANCE trial underway -

MILAN, Italy, Apr 23, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced data from two large Phase 2b clinical trials evaluating the investigational hepatitis C virus (HCV) protease inhibitor telaprevir (VX-950), dosed in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) in treatment-naive, genotype 1-infected HCV patients. Final results from PROVE 1 and further interim analysis from PROVE 2 showed consistently higher SVR rates and antiviral response in the 24-week telaprevir arms -- 61% of patients in PROVE 1 and 68% of patients in PROVE 2 achieving SVR, compared with 41% of patients in the PROVE 1 control arm achieving SVR and 48% of patients in the PROVE 2 control arm having undetectable HCV RNA at 12 weeks post-treatment. These data will be presented at the 43rd Annual Meeting of the European Association for the Study of the Liver in Milan, Italy from April 23-27, 2008.

"Patients in the completed PROVE 1 study, and those thus far reported in an interim assessment of PROVE 2 who received a telaprevir-based regimen for 12 weeks, followed by 12 weeks of pegylated interferon and ribavirin, achieved SVR rates approximately 20% higher than the SVR 24 (PROVE 1) or SVR 12 (PROVE 2) seen in the 48-week control arms and demonstrated the potential of telaprevir to produce sustained viral responses in greater numbers of patients," said John McHutchison, M.D., Principal Investigator for the PROVE 1 trial and Associate Director of the Duke Clinical Research Institute. "In the Phase 3 ADVANCE trial we will further evaluate the potential of telaprevir to increase SVR and shorten duration."

Low Relapse Rates Observed with 24-week Telaprevir-Based Regimens

In PROVE 1 and PROVE 2, a combined relapse rate of 5% (2% in PROVE 1 and 7% in PROVE 2) was reported in patients treated with a 24-week telaprevir-based treatment regimen who were undetectable at week 4 and week 12 (HCV RNA less than10 IU/mL). In the 48-week control arms, a relapse rate of 23% was observed in PROVE 1 at 24 weeks post-treatment and a relapse rate of 20% was observed in PROVE 2 at 12 weeks post-treatment. At the time of the analysis, only 12-week post-treatment relapse data were available for patients in the PROVE 2 control arm. SVR calculations include some patients who did not complete the full course of therapy, and therefore are not included in the relapse rate calculation.

"In the treatment arms that included telaprevir, pegylated interferon and ribavirin, a high percentage of patients who had undetectable virus at week 4 and 12 developed a sustained viral response," said Dr. Geoffrey M. Dusheiko, Investigator for PROVE 2 and Professor of Medicine at Royal Free Hospital and University College London Institute of Hepatology. "If these results are validated in Phase 3 studies, shorter courses of treatment for a larger percentage of treatment-naive hepatitis C genotype 1 infected patients may be possible."

Telaprevir Safety & Tolerability Consistent with Prior Analyses

In Phase 2 clinical studies to date, more than 700 patients have received a telaprevir containing regimen, and the adverse event profile is generally consistent across studies and prior analyses. In the PROVE 1 and PROVE 2 studies, telaprevir is being evaluated in combination with Peginterferon alfa-2a and Ribavirin for the treatment of patients chronically infected with hepatitis C virus (HCV) genotype 1. In these placebo-controlled studies, the most common adverse events reported more frequently in the telaprevir treatment arms compared to the placebo arms were gastrointestinal events, skin events (rash, pruritus) and anemia. Other adverse events reported were similar in type and frequency to those seen currently with peg-IFN/RBV treatment.

Treatment discontinuation rates in the combined data through week 24 of treatment due to adverse events were 17% in the telaprevir treatment arms. In the control arms, 10% of patients discontinued treatment during the 48-week treatment period. The most common adverse event leading to discontinuation in the telaprevir arms was rash in 7% of patients across both PROVE 1 and PROVE 2. Investigators have reported that the rash resolves upon discontinuation of telaprevir.

Telaprevir Data Presentations at EASL Meeting

Oral Presentations:

"PROVE 1: Results From a Phase 2 Study of Telaprevir with Peginterferon alfa-2a and Ribavirin in Treatment-Naive Subjects with Hepatitis C," on Thursday, April 24th at 3:45 p.m. CEST (9:45 a.m. EDT).

"Treatment of Chronic Hepatitis C with Telaprevir (TVR) in Combination with Peginterferon-alfa-2a with or without Ribavirin: Further Interim Analysis Results of the PROVE2 Study," on Friday, April 25th at 11:45 a.m. CEST (5:45 a.m. EDT).

Late-Breaker Poster Presentation:

"A Study of Telaprevir (TVR) with Peginterferon alfa-2A (P) and Ribavirin (R) in Subjects with Well-documented Prior P/R Null Response, Non-Response or Relapse: Preliminary Results" starting on Thursday, April 24.

Poster Presentation:

"Natural Prevalence Of HCV Variants with Decreased Susceptibility to NS34a Protease Inhibitors in Treatment-Naive Subjects," starting on Thursday, April 24.

About PROVE 1 and PROVE 2

PROVE 1 is a four-arm, Phase 2b clinical trial of 250 treatment-naive genotype 1 HCV patients with a primary objective to assess the proportion of patients who achieve SVR, defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan(R) assay) HCV RNA 24 weeks after the completion of dosing. The study is assessing patients who receive telaprevir-based treatment regimens of 12, 24 and 48-week durations, compared to a 48-week control arm of pegylated interferon and ribavirin. PROVE 1 is being conducted at 37 clinical centers in the U.S.

PROVE 2 is an ongoing, four-arm, Phase 2b clinical trial of 323 treatment-naive genotype 1 HCV patients with a primary objective to assess the proportion of patients who achieve SVR. The study is assessing patients who receive telaprevir-based treatment regimens of 12 and 24-week durations and a 12-week arm without ribavirin, compared to a 48-week control arm of pegylated interferon and ribavirin. PROVE 2 is being conducted at 28 clinical centers in Europe.

About Telaprevir and ADVANCE Phase 3 Clinical Development

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is the most advanced investigational agent in development that specifically targets HCV. Telaprevir is the first hepatitis C protease inhibitor in Phase 3 clinical development. The ongoing ADVANCE trial is a global, 3-arm pivotal controlled trial designed to evaluate two 24-week telaprevir-based regimens in approximately 1050 treatment-naive genotype 1 HCV patients. In this study, extended RVR criteria (undetectable HCV RNA at week 4 and week 12) will be used to determine which telaprevir patients can stop all treatment at 24 weeks. In addition to ADVANCE, Vertex is conducting a global Phase 2b clinical development program of telaprevir, including PROVE 1 and PROVE 2 in treatment-naive genotype 1 HCV patients, and PROVE 3 in genotype 1 HCV patients who have not achieved SVR with a prior course of pegylated interferon-based therapy. In these clinical trials, telaprevir is being dosed as 750 mg every eight hours in combination with pegylated interferon alfa-2a (Pegasys(R)) both with and without ribavirin (Copegus(R)).

Vertex retains commercial rights to telaprevir in North America. Vertex and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East and other countries. 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 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 HCV infection may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Chronic HCV 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 typically provide sustained benefit in less than half of patients with genotype 1 HCV, the most common strain of the virus.

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 cystic fibrosis. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

Vertex's press releases are available at www.vrtx.com.

Safe Harbor Statement

This press release contains forward-looking statements, including the statements that (i) telaprevir data from the PROVE 1 and PROVE 2 clinical trials will be presented at EASL from April 23-27, (ii) the data demonstrated the potential of telaprevir to produce sustained viral response in greater numbers of patients, (iii) in the Phase 3 ADVANCE trial we will further evaluate the potential of telaprevir to increase SVR and shorten duration, (iv) if the reported results are validated in Phase 3 studies, shorter courses of treatment for a larger percentage of treatment-naive hepatitis C genotype infected patients may be possible, and (vi) the clinical trial design for Vertex's Phase 3 ADVANCE clinical trial will be as described in this press release. While the Company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that the outcomes for our planned telaprevir clinical trials and studies may not be favorable, that there may be varying interpretations of data produced by one or more of our clinical trials, and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at www.vrtx.com. We disclaim any obligation to update the information contained in this press release as new information becomes available.

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SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated
Michael Partridge, 617-444-6108
Senior Director, Strategic Communications
or
Patricia Farrell, 617-444-6533
Director, Public Relations
or
Lora Pike, 617-444-6755
Manager, Investor Relations
or
Zachry Barber, 617-444-6470
Manager, Media Relations