June 9, 2008

Vertex Reports 52% SVR 12 Rate for a 24-week Telaprevir-based Regimen in Genotype 1 Hepatitis C Patients Who Failed Prior Treatment

-- 73% of prior relapsers achieved SVR12 with 24-week telaprevir-based treatment

-- 41% of prior non-responders achieved SVR12 with 24-week telaprevir-based regimen

CAMBRIDGE, Mass., Jun 09, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced positive results from a planned interim analysis of PROVE 3, an ongoing Phase 2b study evaluating telaprevir-based treatment in patients with genotype 1 chronic hepatitis C virus (HCV) infection who did not achieve sustained virologic response (SVR) with at least one prior pegylated interferon (peg-IFN) and ribavirin (RBV) regimen. Vertex is developing telaprevir in collaboration with Tibotec.

In the interim analysis, 52% (60 of 115; intent-to-treat analysis) of patients randomized to receive treatment with a 24-week telaprevir-based regimen (12 weeks of telaprevir in combination with peg-IFN and RBV, followed by 12 weeks of peg-IFN and RBV alone) maintained undetectable HCV RNA 12 weeks post-treatment (SVR 12). In the interim analysis, adverse events were similar to those commonly observed with peg-IFN and RBV including fatigue, nausea, rash, headache, gastrointestinal disorders and anemia, and were consistent with those previously reported in patients being treated with telaprevir-based therapy in the PROVE 1 and 2 studies in treatment-naive subjects.

Based on these data, Vertex and Tibotec plan to initiate a Phase 3 clinical trial in patients who have failed prior treatment with peg-IFN and RBV. Telaprevir (TVR) is the most advanced HCV protease inhibitor in clinical development targeting treatment of chronic hepatitis C, and is in Phase 3 clinical development in treatment-naive patients. Hepatitis C is a disease that afflicts more than 3 million people in the United States alone, and 170 million worldwide.

Interim Analysis Results

PROVE 3 is a randomized, double-blind, placebo-controlled Phase 2b study that enrolled patients who failed prior treatment with peg-IFN and RBV. Patients enrolled in PROVE 3 included prior non-responders (including null responders), prior relapsers and prior breakthroughs to peg-IFN and RBV treatment. The interim analysis included 453 patients that were enrolled and received at least one dose of study drug. In the interim analysis, 52% (60 of 115) of patients randomized to receive a 24-week telaprevir-based regimen (12 weeks of telaprevir in combination with peg-IFN and RBV, followed by 12 weeks of peg-IFN and RBV alone) achieved undetectable HCV RNA (less than 10 IU/mL; Roche TaqMan) 12 weeks post-treatment (SVR12). Of the 115 patients, 66 were categorized as non-responders to prior treatment (defined as patients who never achieved undetectable HCV RNA during prior treatment, including null responders), 40 were prior relapsers (defined as patients who had undetectable HCV RNA at the completion of prior treatment, but relapsed during follow-up), and 9 were prior breakthroughs (defined as patients who had viral rebound during prior treatment). Among patients receiving the 24-week telaprevir-based regimen, 41% (27 of 66) of the prior non-responders, 73% (29 of 40) of prior relapsers, and 44% (4 of 9) of prior breakthroughs achieved SVR 12.

"Patients who have not achieved a sustained virologic response with one or more courses of prior interferon-based therapy represent a significant unmet medical need. These patients have few or no available treatment options and they are at increased risk for progressive liver disease," said John McHutchison, M.D., Principal Investigator for the PROVE 3 Study and Associate Director of Duke Clinical Research Institute.

A summary of available on-treatment and post-treatment antiviral data from the 24-week telaprevir-based regimen is presented below:

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Undetectable HCV-RNA by Response to Prior Peg-IFN/RBV Treatment (PROVE
  3 24-week regimen; 12 weeks telaprevir+peg-IFN+RBV, followed by 12
             weeks peg-IFN+RBV); intent-to-treat analysis
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	Week 12	Week 24 (end of treatment)	SVR 12 (week 36; 12 weeks post-treatment)
Non-responders (n=66)	71%	65%	41%
Relapsers (n=40)	88%	83%	73%
Breakthroughs (n=9)	44%	44%	44%
Total (n=115)	75%	70%	52%

In the control arm (n=114), which is evaluating 48 weeks of peg-IFN and RBV only, available data indicate that 8% of patients had undetectable HCV RNA at week 12, and 30% had undetectable HCV RNA at week 36 on-treatment (intent-to-treat analysis). In prior studies of peg-IFN and RBV in treatment-failure patients, the proportion of patients who had undetectable HCV RNA at week 36 of treatment has been significantly higher than the proportion who ultimately achieved SVR. End-of-treatment and post-treatment data (including SVR rates) are not yet available for this study arm in PROVE 3.

In addition to the 24-week telaprevir-based regimen that includes ribavirin and the 48 week control arm described above, two other treatment regimens are being evaluated in PROVE 3: a 24-week telaprevir treatment arm without ribavirin, and a 48-week treatment arm that includes 24 weeks of telaprevir dosing in combination with peg-IFN and RBV. The interim analysis supports the inclusion of ribavirin in future studies of telaprevir-based regimens in treatment-failure patients, similar to what has been observed in treatment-naive subjects. In addition, available on-treatment results suggest that additional dosing of telaprevir beyond 12 weeks does not confer additional benefit to patients. Patient dosing has now been completed in PROVE 3 and all patients are now being followed post-treatment. Vertex anticipates that PROVE 3 data will be the subject of a presentation at a medical conference later in 2008.

"These are the first data to show the potential of a STAT-C agent to have this degree of antiviral response in patients--including both non-responders and relapsers--who did not achieve SVR with prior treatment. The interim data suggest that a telaprevir-based regimen could be an important future treatment option for genotype 1 hepatitis C patients who have failed a prior course of treatment," said John Alam, M.D., Executive Vice President, Medicines Development, and Chief Medical Officer of Vertex. "We are now planning to begin a Phase 3 clinical trial with telaprevir in patients who failed prior peg-IFN and ribavirin treatment."

In the interim analysis, adverse events were similar to those commonly observed with peg-IFN and RBV including fatigue, nausea, rash, headache, gastrointestinal disorders and anemia, and were also consistent with those previously reported in patients being treated with telaprevir-based therapy in the PROVE 1 and 2 studies in treatment-naive subjects. Thirteen patients (11%) receiving the 24-week telaprevir based treatment regimen (12 weeks of telaprevir in combination with peg-IFN and RBV, followed by 12 weeks of peg-IFN and RBV alone) discontinued treatment due to adverse events. The most common reason for discontinuation among patients receiving this 24-week telaprevir-based treatment regimen was rash (7% of patients). In the control arm, 5 patients (4%) discontinued treatment prior to week 36 due to adverse events.

Phase 3 Study in Patients Who Failed Prior Treatment

Vertex and Tibotec plan to initiate a Phase 3 clinical trial in genotype 1 HCV patients who have failed prior treatment with peg-IFN and RBV in the third quarter, which will be led by Tibotec. The randomized, double-blind and placebo-controlled study will focus on regimens of 48 weeks total treatment duration, in which telaprevir is administered for 12 weeks, with a goal of maximizing SVR rates. The study is planned to be conducted at more than 50 centers in the U.S., E.U. and certain other countries.

Updates on the status of Vertex and Tibotec's clinical trials of telaprevir are available at www.clinicaltrials.gov.

About PROVE 3

PROVE 3 is an ongoing, four-arm, Phase 2b clinical trial of 453 genotype 1 HCV patients who did not achieve an SVR with a prior course of peg-IFN and RBV treatment. The study includes patients with compensated cirrhosis. The study is assessing patients who receive telaprevir-based treatment regimens of 24 and 48-week total duration, compared to a 48-week control arm of peg-IFN and RBV. PROVE 3 is being conducted at 50 clinical centers in the U.S. and the E.U.

About Telaprevir (VX-950)

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 trials. The Phase 3 ADVANCE trial is expected to enroll 1,050 treatment-naive genotype 1 HCV patients and will evaluate two 24-week telaprevir-based regimens in comparison to a 48-week control arm. Vertex is also 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.

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 and Treatment-Failure Patients

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. 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. As many as 250,000 patients in the United States have received at least one course of treatment with pegylated interferon and ribavirin but have not achieved SVR. Patients who have failed interferon-based treatment typically have few or no available treatment options, and are at risk for progessive liver disease. In a recent study, the risk of liver failure, cancer or death following unsuccessful HCV treatment was 23% after 4 years, and 43% after 8 years. (1).

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.

1. Veldt et al, "Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis," Annals of Internal Medicine, 20 November 2007; 147: 677-684.

Safe Harbor Statement

This press release contains forward-looking statements, including statements (i) that based on the interim results disclosed in this press release Vertex and its collaborator plan to initiate a Phase 3 clinical trial in patients who have failed prior treatment with peg-IFN and RBV, (ii) that available on-treatment results suggest that additional dosing of telaprevir beyond 12 weeks does not confer additional benefits to patients, (iii) that Vertex anticipates that PROVE 3 data will be the subject of a presentation at a medical conference later in 2008, (iv) that the interim data suggests that a telaprevir-based regimen could be an important future treatment option for genotype 1 hepatitis C patients who have failed a prior course of treatment, (v) that based on this interim data, Vertex will be able to demonstrate in PROVE 3 a significant difference in SVR rates with telaprevir-based treatment compared to current treatments, in both non-responders and relapsers, (vi) regarding the design of the Phase 3 clinical trial in treatment experienced patients that Vertex plans to commence in the third quarter and (vii) regarding the Phase 3 ADVANCE clinical trial that Vertex is conducting in treatment-naive patients. 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 (a) the promising interim data from the PROVE 3 clinical trial, including the viral response rates from 12 weeks post-treatment, will not be confirmed by final data from the PROVE 3 treatment and control arms, which will require viral response rates 24 weeks post-treatment, or by data obtained from future clinical trials, (b) the outcomes for our planned telaprevir clinical trials and studies may not be favorable, (c) the commencement of future clinical trials may be delayed or the anticipated trial design may need to be altered, (d) that there may be varying interpretations of data produced by one or more of our clinical trials, and (e) 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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