April 25, 2009

Telaprevir Data Presented at EASL Show Unprecedented SVR Rates in HCV Treatment-Failure Patients in PROVE 3 Study

- Superior SVR rates with telaprevir across all HCV genotype 1 non-responders and relapser patients and patients with cirrhosis - up to 76% in prior relapsers -- PROVE 3 showed 51% and 52% SVR rates in telaprevir-based regimens compared to 14% in the 48-week control arm-- Treatment-failure patient population represents the greatest unmet medical need in HCV -

COPENHAGEN, Apr 25, 2009 (BUSINESS WIRE) -- Unprecedented sustained viral response (SVR) rates were achieved in hepatitis C-infected treatment-failure patients, including those with cirrhosis, with telaprevir-based treatment according to PROVE 3 trial results presented today in the late breaker session at the 44th Annual Meeting of the European Association for the Study of the Liver (EASL) in Copenhagen, Denmark. Telaprevir is being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) in collaboration with Tibotec and Mitsubishi Tanabe Pharma.

In this intent-to-treat analysis, 51% and 52% of treatment-failure patients achieved SVR in the 24-week and 48-week telaprevir-based regimens, respectively. In comparison, SVR rates were achieved by 14% of patients randomized to receive 48 weeks of peg-IFN and RBV alone. Adverse events were generally consistent with those reported in prior telaprevir Phase 2 trials.

"Previously treated patients who didn't achieve SVR represent the hardest to treat patient population in physicians' practices," said Michael P. Manns, M.D., Principal Investigator for the PROVE 3 Study and Director of the Department of Gastroenterology, Hepatology and Endocrinology at Medical School of Hannover, Germany. "Today's compelling PROVE 3 results represent important progress as we seek to address a serious unmet need in patients who currently have very few options. We observed superior SVR rates across all telaprevir-based treatment arms compared to the control arm in patients who had previously failed treatment for hepatitis C, including patients with cirrhosis. This represents an exciting potential medical advance."

"The SVR rates achieved in this difficult-to-treat population, with safety results consistent with prior telaprevir studies, add to the growing body of data supporting further development of telaprevir across the broad HCV patient population," said Freda Lewis-Hall, M.D., Executive Vice President, Medicines Development and Chief Medical Officer at Vertex. "Telaprevir is the only STAT-C agent to show SVR rates at this level in the treatment-failure patient group."

PROVE 3 SVR Results

PROVE 3 was 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, prior relapsers and prior breakthroughs to peg-IFN and RBV treatment. The results included 453 patients who were enrolled and received at least one dose of study drug.

A summary of available on-treatment and post-treatment antiviral data from the 24-week telaprevir-based regimen compared to the 48-week standard of care regimen is presented below:

PROVE 3 Sustained Viral Response rates; intent-to-treat analysis

	TVR12/PR24	**TVR24/PR48**	**PR48**
Non-responders [1]	39% (n=66)	38% (n=64)	9% (n=68)
Relapsers [2]	69% (n=42)	76% (n=41)	20% (n=41)
Breakthroughs [3]	57% (n=7)	50% (n=8)	40% (n=5)
Total	51% (n=115)	52% (n=113)	14% (n=114)

[1] Non-responders are defined as patients who never achieved undetectable HCV RNA during or at the end of prior therapy.
[2] Relapsers are defined as patients who achieved undetectable HCV RNA at the completion of prior treatment, but relapsed during follow-up.
[3] Breakthroughs are defined as patients who had undetectable HCV RNA during prior treatment, but had detectable HCV RNA before the end of prior treatment.

Sixty-nine and 76% of prior relapsers in the 24- and 48-week telaprevir-based treatment arms, respectively, achieved SVR as compared to 20% in the control arm, and 39% and 38% of prior non-responders in the 24- and 48-week telaprevir-based

treatment arms, respectively, achieved SVR as compared to 9% in the control arm. A sub-analysis showed that 53% and 45%, respectively, of patients with cirrhosis in the 24- and 48-week telaprevir-based treatment arms achieved SVR compared to 8% in the control arm - these results were similar to those obtained for patients without cirrhosis.

In PROVE 3, an overall relapse rate of 13% (10 of 76 patients) was observed in patients in the 48-week telaprevir-based treatment regimen arm, while patients in the control arm relapsed at a rate of 53% (18 of 34 patients). A third arm of the study, evaluating a 24-week telaprevir-based regimen, showed a similar SVR rate compared to the 48-week telaprevir arm and an overall relapse rate of 30% (26 of 87 patients). In a completers' analysis, a relapse rate of 4% (2 of 53 patients) was observed in patients who completed treatment with a 48-week telaprevir-based treatment regimen, while patients who completed treatment in the control arm relapsed at a rate of 52% (17 of 33 patients). A third arm of the study, evaluating a 24-week telaprevir-based regimen, had a relapse rate of 28% (22 of 80 patients) in patients who completed treatment with a 24-week telaprevir-based regimen. These results suggest that a telaprevir-based regimen that includes a total of 48 weeks of treatment with peg-IFN and RBV including 12 weeks of telaprevir may be warranted in treatment-failure patients. REALIZE, a Phase 3 study designed to evaluate this treatment regimen in non-responders (null and partial responders) and relapsers, is currently underway.

Safety and Tolerability in PROVE 3

In PROVE 3, adverse events were generally consistent with those reported in prior Phase 2 telaprevir trials including fatigue, nausea, headache, rash, pruritus, diarrhea, insomnia, pyrexia, alopecia, and chills. In the PROVE 3 telaprevir treatment arms, rash led to discontinuations in 5% of patients (17 of 339) and was manageable and reversible upon cessation of treatment. A 1% discontinuation rate due to anemia (3 of 339) was observed which was similar to that in the control arm. Erythropoiesis stimulating agents (ESA) were not recommended for the PROVE 3 study and were rarely used (in less than 1% (2 of 339) of patients) in the telaprevir-based treatment arms.

About Telaprevir

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 antiviral agents in development that specifically targets HCV. Telaprevir is in Phase 3 clinical trials in treatment-naive and treatment-failure patients.

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 Tanabe 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. 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 sustained virologic response (SVR). Patients who have failed interferon-based treatment typically have few or no available treatment options, and are at risk for progressive 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, cystic fibrosis, inflammation, autoimmune diseases, cancer, and pain. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

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

(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.

Special Note Regarding Forward Looking Statements

This press release contains forward-looking statements, including statements regarding (i) the treatment-failure patient population representing the greatest unmet medical need in HCV and (ii) the compelling PROVE 3 results representing important progress as the Company seeks to address a serious unmet need in patients who currently have very few options. 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 each of its clinical trials of telaprevir (including the ongoing Phase 3 REALIZE clinical trial) may not be favorable, that future competitive or other market factors may adversely affect the commercial potential for the Company's product candidates in HCV 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. The Company disclaims any obligation to update the information contained in this press release as new information becomes available.

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