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First Studies Demonstrating Greater than Sixty Percent Sustained Viral Response Rates with Half the Standard Treatment Duration in Genotype 1 Chronic Hepatitis C Patients

Two Large Phase 2 Trials of Telaprevir, an Investigational Hepatitis C Protease Inhibitor, Dosed in Combination with Pegylated Interferon and Ribavirin Show SVR Rates of 61% and 65% Initial Rapid Viral Decline Appears Important to Achieve SVR Safety Profile Consistent with Prior Interim Analyses

BOSTON, Nov 02, 2007 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced results from interim analyses of PROVE 1 and PROVE 2, two large Phase 2b clinical trials evaluating the investigational hepatitis C protease inhibitor telaprevir (VX-950), dosed in combination with pegylated interferon and ribavirin. In 24-week telaprevir-based treatment regimens, genotype 1 treatment-naive HCV patients achieved sustained viral response rates of 61% and 65% in PROVE 1 (SVR 12 and SVR 24) and PROVE 2 (SVR 12), respectively. In addition, clinical researchers reported a correlation between achieving rapid viral response (RVR) and achieving SVR in a 24-week telaprevir-based regimen.

Interim analyses of telaprevir safety from PROVE 1 and PROVE 2 appear consistent with prior analyses, with the most common adverse events, regardless of treatment assignment, being fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were higher in the telaprevir arms compared to the control arm over the dosing period. Data from PROVE 1 and PROVE 2 being presented at the 58th Annual Meeting of the American Association of the Study of Liver Diseases (AASLD) in Boston November 2-6, 2007 represent interim analyses. Vertex is developing telaprevir, an investigational hepatitis C protease inhibitor, in collaboration with Tibotec.

"The SVR data from the PROVE studies are promising as the expectation today is that approximately 40% to 50% of people with genotype 1 hepatitis C who undergo 48-week treatment regimens with currently available therapies achieve sustained viral response (SVR). In this Phase 2 study, we saw 24-week telaprevir-based regimens result in SVR of greater than 60% in patients with genotype 1 hepatitis C," said John McHutchison, M.D., Principal Investigator for the PROVE 1 study and Director of Gastroenterology and Hepatology Research at Duke Clinical Research Institute. "If these efficacy results are confirmed in larger studies, and there are no new safety or tolerability concerns, this 24-week regimen could be an important medical advance."

Sustained Viral Response in PROVE Studies:

Sustained viral responses (SVR) across PROVE 1 and PROVE 2 are outlined in the table below:

Treatment Arm (Study)	ITT SVR Rate
24-week treatment arm (PROVE 1), n=79	61%
24-week treatment arm (PROVE 2), n=81	65%(a)
12-week treatment arm with ribavirin (PROVE 1), n=17	35%
12-week treatment arm with ribavirin (PROVE 2), n=82	59%

ITT= Intention-to-treat; missing=failure

(a)SVR12: undetectable HCV RNA <10 IU/mL at 12 weeks post-treatment and is an interim measurement. Other data represent SVR 24, defined as undetectable HCV RNA < 10 IU/mL at 24 weeks post-treatment. Across all the treatment arms above, there were no relapses between 12 and 24 weeks follow-up, i.e. there was 100% concordance between SVR 12 and SVR 24.

In addition, the SVR rate in the 12-week arm without ribavirin (n=78) in PROVE 2 was 29%.

In the 48-week telaprevir treatment arm (12+36; n=79) of PROVE 1, 65% had undetectable HCV RNA (<10 IU/mL) at end of treatment.

Sustained viral response results from the control arms of PROVE 1 and PROVE 2 are not available. At the time of the interim analysis, in the PROVE 1 control arm (n=75), 45% of patients receiving 48-weeks of pegylated interferon (peg-IFN) and ribavirin (RBV) had undetectable HCV RNA (<10 IU/mL) at end of treatment. At the time of the interim analysis, in the control arm of PROVE 2 (n=82), 59% of patients receiving 48 weeks of peg-IFN and RBV had undetectable HCV RNA (<10 IU/mL) at week 36 on-treatment. Typically, following the completion of 48 weeks of treatment with peg-IFN+RBV, a certain proportion of patients with undetectable HCV RNA relapse.

SVR rates given for the telaprevir arms include patients who completed dosing in their study arm as well as patients who discontinued treatment prior to completion of dosing, but who met the criteria for SVR 24 (defined as undetectable HCV RNA <10 IU/mL 24 weeks after completing treatment).

SVR results for the telaprevir 12+36-week treatment arm in PROVE 1 and the control arms for PROVE 1 and PROVE 2, including viral relapse observed post-treatment, will be presented at a future medical meeting. A detailed overview of the PROVE 1 and PROVE 2 clinical trial designs can be found in a Vertex press release dated May 23, 2006.

Rapid Viral Response (RVR)

In PROVE 1 and PROVE 2 combined, on an ITT basis, 77% of patients receiving telaprevir in combination with peg-IFN and RBV achieved a rapid viral response at 4 weeks (79% in PROVE 1, 75% in PROVE 2), defined as undetectable HCV RNA <10 IU/mL as measured by the Roche TaqMan(R) assay, compared to an average of 12% of patients across the control arms of PROVE 1 and PROVE 2 (11% in PROVE 1, 13% in PROVE 2; p<0.001 for the comparison in each study).

For those patients that achieved RVR, completed 24 weeks of telaprevir-based therapy, and had data available for SVR analysis, 91% achieved an SVR 24 or SVR 12. This finding demonstrates a correlation between RVR and SVR in a 24-week telaprevir-based treatment regimen.

Viral Breakthrough

In PROVE 1 and PROVE 2 combined, 5% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough in the first 12 weeks of treatment (7% in PROVE 1, 2% in PROVE 2). Most viral breakthroughs occurred in the first month of treatment, and were generally associated with low interferon blood levels. After patients had undetectable HCV RNA (<10 IU/mL), less than 2% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough on treatment.

Viral Relapse

In PROVE 1 and PROVE 2 combined, the relapse rate for patients who completed 24 weeks of treatment was 9% (2% in PROVE 1, 14% in PROVE 2). In PROVE 1 and PROVE 2 combined, for those patients that achieved an RVR and completed 24 weeks of therapy, 7% experienced viral relapse in the post-treatment period (2% in PROVE 1, 11% in PROVE 2). Per protocol in PROVE 1, only patients who achieved an RVR were to stop treatment at 24 weeks of therapy; no such criteria were utilized in PROVE 2. Following completion of treatment, no patient in PROVE 1 that received telaprevir in combination with peg-IFN and RBV relapsed after week 12 of the 24-week post-treatment period.

PROVE 1 and PROVE 2 Safety

The types of adverse events that have been commonly observed with Peg-IFN and RBV were seen across all treatment arms of PROVE 1 and PROVE 2. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were higher in the telaprevir arms compared to the control arm over the dosing period.

In PROVE 1, the overall discontinuation rate through 12 weeks was 18% across all telaprevir treatment arms and 3% in the control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events was 13% and 2% in the telaprevir and control arms, respectively. The most common reason for discontinuation was rash, with 7% of patients discontinued for this reason in the telaprevir arms during the first 12 weeks of treatment. After week 12, discontinuations due to adverse events were 8% each in the telaprevir and control arms. Over the full course of the treatment period, the incidence of severe adverse events was 27% in the telaprevir arms and 24% in the control arm.

In PROVE 2, the overall discontinuation rate through 12 weeks was 14% across all telaprevir treatment arms and 6% in the

control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events were 10% and 3% in the telaprevir and control arms, respectively. As with PROVE 1, the most common reason for discontinuation was rash, with 7% of patients discontinued due to rash in the telaprevir arms, compared to less than one percent in the control arm during the first 12 weeks of treatment. Through to week 12, the time of the interim safety analysis being reported, the incidence of severe adverse events was 17% in the telaprevir arms and 10% in the control arm.

About PROVE 1

PROVE 1 is an ongoing, 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 than10 IU/mL, as measured by the Roche TaqMan(R) assay) HCV RNA 24 weeks after the completion of dosing. The trial 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 more than 30 clinical centers in the U.S.

Baseline patient characteristics were similar across telaprevir treatment and control arms in PROVE 1. Twenty percent of those treated with telaprevir were either Hispanic (10%) or African American (10%). In the control arm, 8% of patients were Hispanic and 12% were African American. Median HCV RNA at entry was similar across all arms (6.6 Log10IU/mL in telaprevir treatment arms and 6.7 Log10IU/mL in control) and 87% of patients had a high viral load, defined as >800,000 IU/mL. On average, patients were 49 years old (21-63 years range) with a mean weight of 82.1kg (46-136kg range).

About PROVE 2

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, 24 and 48 week durations, compared to a 48-week control arm. PROVE 2 is being conducted at more than 40 clinical centers in Europe.

The median baseline viral load for patients in PROVE 2 was 6.4 Log10IU/mL (3.3-7.7) and 83% of patients had a high viral load, defined as >800,000 IU/mL. The majority of patients were male (94.1%), Caucasian (94.1%) and infected with genotype 1b (54.1%) compared to genotype 1a (34.1%). On average, patients were 45 years old (18-65 years range) with a mean weight of 70.9kg (45-115kg range).

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. Vertex is conducting a global Phase 2b clinical development program for telaprevir consisting of three large clinical trials that enrolled approximately 1,000 patients with genotype 1 HCV at clinical centers in the United States, Canada and Europe. 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)). The data from PROVE 1 and PROVE 2 being presented at AASLD represent interim analyses, and Vertex continues to gather information on the safety and antiviral effect of telaprevir-based therapy to determine appropriate regimens and durations for evaluations in further trials.

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 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 early 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.

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

About Tibotec

Tibotec Pharmaceuticals, Ltd., based in Cork, Ireland, is a pharmaceutical research and development company. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS drugs and anti-infectives for diseases of high unmet medical need. The Company's main research and development facilities are in Mechelen, Belgium with offices in Yardley, PA.

For further information on Tibotec, please visit www.tibotec.com

Safe Harbor Statement

This press release may contain forward-looking statements, including statements that (i) a 24-week therapy regimen could be an important medical advance if confirmed in larger studies in the future; and (ii) SVR results from the 12+36-week arm of PROVE 1 and from the control arms of both PROVE 1 and PROVE 2 will be presented at a future medical meeting. 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 observed outcomes in clinical investigations of smaller numbers of patients will not be reflected in clinical trials involving larger numbers of patients, that unexpected and adverse outcomes in ongoing clinical and nonclinical studies will occur, that the FDA or other regulatory authorities will require additional and unanticipated studies or clinical trial outcomes before granting regulatory approval, and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 1, 2007. Vertex disclaims any obligation to update the information contained in this press release as new data become available.

(VRTX - GEN)

SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated
Lynne H. Brum, 617-444-6614
VP, Strategic Communications
or
Michael Partridge, 617-444-6108
Director, Corporate 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
Senior Media Relations Specialist