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New Clinical Data Support Broad Profile for Telaprevir in Patients with Genotype 1 Hepatitis C Virus (HCV) Infection

- PROVE 3 data show 52% SVR12 in HCV treatment-failure patients with 24-week treatment duration
- PROVE 2 final results confirm 69% SVR in HCV treatment-naïve patients with 24-week treatment duration
- C208 study interim analysis supports potential for future twice-daily telaprevir dosing

SAN FRANCISCO--(BUSINESS WIRE)--New clinical data from four Phase 2 clinical trials of the investigational hepatitis C protease inhibitor telaprevir (VX-950) to be presented at the 59th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco support a broad profile for telaprevir in the treatment of chronic genotype 1 hepatitis C virus infection. Telaprevir is being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) in collaboration with Tibotec.

"Data from Phase 2 telaprevir clinical studies in genotype 1 HCV patients are encouraging as responses were seen in treatment-naïve patients, as well as in those who had previously failed treatment with the current standard of care regimen," said John McHutchison, M.D., Principal Investigator for the PROVE 3 study and Associate Director of the Duke Clinical Research Institute. "PROVE 3 data showed that a telaprevir regimen produced a 52% SVR12 in treatment-failure subjects, which is noteworthy as patients who have failed therapy are very difficult to manage due to limited available treatment options and are at greater risk for developing progressive liver disease."

"The data being presented at AASLD support the potential for telaprevir to have a broad role in genotype 1 HCV patients, including those naïve to treatment and those who have previously failed one or more courses of pegylated interferon and ribavirin," said Freda Lewis-Hall, M.D., Executive Vice President, Medicines Development at Vertex. "In addition to the positive data seen in treatment-failure patients, in the final results from PROVE 2 we see the potential for a significant proportion of treatment-naïve genotype 1 HCV patients to achieve SVR with a 24-week telaprevir-based regimen."

PROVE 3 Interim Analysis for Patients Who Failed to Achieve SVR with Prior Therapy

The PROVE 3 data show a 52% SVR12 in HCV treatment-failure patients, with a 24-week treatment duration. Results are an interim analysis of a Phase 2b randomized, double-blind, placebo-controlled study in 453 patients who failed prior treatment with pegylated-interferon (peg-IFN) and ribavirin (RBV), including non-responders, prior relapsers and prior breakthroughs. PROVE 3 patient dosing was completed earlier this year and all patients are currently being followed post-treatment.

A summary of PROVE 3 antiviral response rates in one of two 24-week telaprevir-based treatment arms (12 weeks telaprevir in combination with peg-IFN/RBV, followed by 12 weeks peg-IFN/RBV only) categorized by patients' prior response to peg-IFN/RBV treatment is presented below.

PROVE 3 Treatment Arms	Interim Undetectable HCV RNA (<10 IU/mL) in PROVE 3 24-week regimen (intent-to-treat analysis)
	SVR12(4)
Non-responders (n=66)$_{(1)}$	41% (27 of 66)
Relapsers (n=40)$_{(2)}$	73% (29 of 40)
Breakthroughs (n=9)$_{(3)}$	44% (4 of 9)
Total (n=115)	52% (60 of 115)

[1] Non-responders are defined as patients who never achieved undetectable HCV RNA during prior therapy.
[2] Relapsers are defined as patients who achieved undetectable HCV RNA at the completion of prior treatment, but relapsed during post-treatment 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.
[4] SVR12 = undetectable HCV RNA (<10 IU/mL) measured at 12 weeks post-treatment.

In the PROVE 3 control arm (48 weeks of peg-IFN/RBV), 30% (34 of 114) of patients had undetectable HCV RNA at week 36 on treatment (intent-to-treat analysis). At week 12 on treatment, 8% of these patients (9 of 114) had undetectable HCV RNA.

Study 107 Interim Analysis in Treatment-Failure Genotype 1 HCV Patients

In Study 107, a separate study of telaprevir-based regimens in well-characterized treatment-failure patients, researchers found that a high proportion of these patients had a rapid viral response and maintained undetectable HCV RNA (<10 IU/mL) through 24 weeks of treatment, further supporting the role for telaprevir in the treatment-failure population. A large number of patients enrolled in Study 107 had prior null-

response. Interim efficacy results include data for patients who have reached respective visits or who had discontinued therapy for any reason or who became detectable at each timepoint. These interim results from Study 107 are summarized in the table below.

Prior Virologic Response in Phase 2 PROVE control arm Studies[1]	Interim Undetectable HCV RNA (<10 IU/mL) by Response to Prior Peg-IFN/RBV Treatment at Week 4, 12 and 24[1]		
	Week 4 <10 IU/mL	Week 12 <10 IU/mL	Week 24 <10 IU/mL
Null-responder (n=48)[2]	40% (19 of 48)	61% (28 of 46)	43% (18 of 42)
Partial responder (n= 33)[3]	85% (28 of 33)	90% (26 of 29)	82% (18 of 22)
Relapsers (n= 22)[4]	91% (20 of 22)	94% (16 of 17)	83% (5 of 6)
Breakthrough (n=1)[5]	100% (1 of 1)	100% (1 of 1)	0% (0 of 1)

[1] Patients are unique in each of the non-response categories.
[2] Null-responders defined as patients who had less than a 1 log(10) decrease in HCV RNA at week 4 or less than a 2 log(10) decrease in HCV RNA by week 12.
[3] Partial-responders defined as patients who had a greater than or equal to 2 log(10) decrease in HCV RNA at week 12, but had detectable HCV RNA at week 24.
[4] Relapsers defined as patients who had undetectable HCV RNA at the end of treatment, but reverted to detectable levels of HCV RNA during follow-up.
[5] Breakthrough defined as patients who had detectable HCV RNA after achieving undetectable HCV RNA during treatment with standard therapy.

The Study 107 results presented at AASLD represent an interim analysis of the ongoing, open-label Phase 2 study designed to evaluate telaprevir in patients who failed to achieve SVR in the 48-week control arms of the Phase 2 PROVE studies. In Study 107, at entry patients had been well-characterized as null responders, partial responders, relapsers or breakthroughs to prior peg-IFN and RBV treatment as a result of their participation in a prior Vertex PROVE clinical trial. The analysis includes data from all 104 patients enrolled in Study 107 who received at least one dose of study drug and who completed at least the Week 4 assessment. Patients continued treatment at week 4 and 12 if they did not meet the stopping rule criteria, defined as HCV RNA >100 IU/mL and HCV RNA >25 IU/mL (Roche Taqman assay, version 2.0) at week 4 or 12, respectively.

PROVE 2 Final Results in Genotype 1 HCV Treatment-Naïve Patients

PROVE 2 final results confirm 69% SVR in HCV treatment-naïve patients with 24-week telaprevir-based treatment durations. A more detailed summary of final intent-to-treat SVR rates from PROVE 2, a study of 323 genotype 1 treatment-naïve patients, is presented below.

PROVE 2 Treatment Arms	SVR %
24-week telaprevir treatment arm 12 weeks telaprevir/peg-IFN/RBV, followed by 12 weeks peg-IFN/RBV	69% (56/81)
12-week telaprevir treatment arm with ribavirin 12 weeks telaprevir/peg-IFN/RBV	60% (49/81)
12-week telaprevir treatment arm without ribavirin 12 weeks telaprevir/peg-IFN	30% (28/78)
48-week control arm 48 weeks peg-IFN/RBV	46% (38/82)

Safety and Tolerability Across PROVE 3, Study 107 and PROVE 2

In Phase 2 clinical studies to date, more than 1,000 patients with genotype 1 HCV have received a telaprevir-containing combination regimen, and the adverse event profile is generally consistent across studies and prior analyses. In the PROVE 3, Study 107 and PROVE 2 telaprevir studies, the most common adverse events reported more frequently in patients receiving telaprevir were gastrointestinal events, skin events (rash, pruritus) and anemia. There have been reports of severe rashes in clinical studies of telaprevir-based therapy. Other adverse events reported were similar in type and frequency to those reported with peg-IFN and RBV treatment.

In the PROVE 3 interim analysis, 16% of patients in the telaprevir-based treatment arms discontinued due to adverse events prior to week 36, while 4% of patients in the 48-week control arm discontinued treatment in the same time period. Rash was the most common reason for discontinuation in 6% of patients. In the Study 107 interim analysis, 8% of patients discontinued due to adverse events. The most common reason for discontinuation was rash in 4% of patients. In the PROVE 2 final analysis, 14% of patients receiving a 24-week telaprevir-based treatment regimen discontinued all study drugs due to adverse events, compared to 7% in the 48-week control arm. The discontinuation of all treatment in the telaprevir-based treatment arms due to rash was 7%.

Interim Analysis of C208 Study - Evaluation of Twice-Daily Dosing in HCV Genotype 1 Patients

Interim results from an ongoing, Phase 2, open-label, randomized study examining a twice-daily (q12h) telaprevir dosing regimen versus a

three-times-daily (q8h) regimen in combination with RBV and peg-IFN-alfa-2a (PEGASYS®) or peg-IFN-alfa-2b (PEGINTRON™) in treatment-naïve genotype 1 HCV patients suggest the potential for twice-daily dosing of telaprevir. A summary of this interim analysis is shown below:

C208 Treatment Assignment	Interim Undetectable HCV RNA (<10 IU/mL) at Week 4 and 12	
	Week 4	Week 12
q8h alfa-2a (n=40)$_{(1)}$	80% (32 of 40)	93% (37 of 40)
q8h alfa-2b (n=42)$_{(1)}$	69% (29 of 42)	93% (39 of 42)
q12h alfa-2a (n=40)$_{(2)}$	83% (33 of 40)	83% (33 of 40)
q12h alfa-2b (n=39)$_{(2)}$	67% (26 of 39)	85% (33 of 39)

In this analysis, 4 patients (10%) in the q8h alfa-2a and 2 patients (5%) in the q8h alfa-2b arms discontinued due to adverse events and 1 patient (3%) and 3 patients (7%), respectively, experienced virologic breakthrough. In the q12h alfa-2a and q12h alfa-2b arms, 4 patients (10%) and 3 patients (8%), respectively, discontinued due to adverse events, and 2 patients (5%) and 3 patients (8%), respectively, experienced virologic breakthrough.

Phase 3 Registration Programs - ADVANCE and REALIZE

Vertex and Tibotec have completed enrollment in the global 3-arm pivotal Phase 3 ADVANCE trial that is focused on 24-week telaprevir-based response guided regimens in genotype 1 treatment-naïve HCV patients. In the ADVANCE study, telaprevir is being dosed for 8 or 12 weeks. Vertex expects to have SVR data from the ADVANCE study in the first half of 2010.

Patient dosing is underway in the Phase 3 REALIZE clinical study of telaprevir in genotype 1 HCV patients who failed to achieve

SVR with prior treatment of peg-IFN and RBV. This study is focused on 48-week telaprevir-based regimens, which include dosing of telaprevir for 12 weeks. REALIZE is expected to complete enrollment of approximately 650 patients in the United States and Europe in the first quarter of 2009.

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-naïve and treatment-failure patients.

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, 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.

PEGASYS® is a registered trademark of Hoffman La Roche.

PEGINTRON™ is a trademark of Schering Corporation.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding Vertex's expectation that (i) the data being presented at AASLD support a broad profile in the treatment of genotype 1 HCV patients, including those naïve to treatment and those who have previously failed one or more courses of pegylated interferon and ribavirin, (ii) data from Phase 2 telaprevir clinical studies in genotype 1 HCV patients are encouraging, as responses were seen in treatment naive patients, as well as in those who had previously failed treatment with the current standard of care regimen, (iii) the final PROVE 2 indicate the potential for a significant proportion of treatment-naïve genotype 1

HCV patients to achieve SVR with a 24-week telaprevir-based regimen, (iv) the rapid viral response and HCV levels through 24 weeks of treatment in Study 107 further support the role for telaprevir in the treatment-failure population, (v) interim results from the C208 study suggest the potential for twice-daily dosing of telaprevir, (vi) SVR data from ADVANCE will be available in the first half of 2010 and that enrollment in REALIZE will be complete in the first quarter of 2009 and (vii) the burden of liver disease associated with HCV are increasing. 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 planned clinical trials and studies, and in particular its planned clinical trials of telaprevir, may not be favorable, that regulatory authorities may require supplemental clinical trials in order to support registration of telaprevir in any particular indication, that there may be varying interpretations of data produced in one or more of the Company's clinical trials, that enrollment may be more difficult or slower than the Company currently anticipates or that planned clinical trials may not start when planned due to regulatory issues, site startup delays, availability of clinical trial material or other reasons, that regulatory authorities will require more extensive data for a telaprevir NDA filing than currently expected, that future competitive or other market factors may adversely affect the commercial potential for telaprevir, and 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. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

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.

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