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New England Journal of Medicine Publishes PROVE 3 Trial Showing Telaprevir-Based Regimens Significantly Increased Sustained Viral Response (SVR) Rates in Patients Who Did Not Achieve SVR with Prior HCV Therapy

-51% and 53% SVR rates when telaprevir was dosed in combination with pegylated-interferon and ribavirin in treatment-failure patients, compared to 14% SVR rate with pegylated-interferon and ribavirin alone-
-Telaprevir Phase 3 SVR data expected in second quarter 2010 for treatment-naïve patients and third quarter 2010 for treatment-failure patients-
-New Drug Application submission planned for second half of 2010 in treatment-naïve and treatment-failure HCV patients-

CAMBRIDGE, Mass., Apr 07, 2010 (BUSINESS WIRE) -- In a clinical trial known as PROVE 3 published in this week's *New England Journal of Medicine*, treatment with telaprevir-based regimens significantly increased rates of sustained viral response (SVR) in patients with genotype 1 hepatitis C virus (HCV) infection who did not achieve SVR with at least one prior course of pegylated-interferon and ribavirin therapy. In the trial, 51 percent and 53 percent of patients who received telaprevir in combination with pegylated-interferon and ribavirin as part of a 24-week or 48-week regimen, respectively, achieved SVR. In the control arm, 14 percent of patients achieved SVR. Discontinuation of study drugs because of adverse events was more frequent in patients who received a telaprevir-based regimen than in patients who received only pegylated-interferon and ribavirin. Telaprevir is an investigational oral HCV protease inhibitor being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) in collaboration with Tibotec and Mitsubishi Tanabe Pharma. A Phase 3 registration program for telaprevir is nearing completion, and Vertex plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) for telaprevir in the second half of 2010 for both treatment-naïve and treatment-failure patients.

Chronic HCV infection affects up to 3.9 million individuals in the United States.[1] Approximately 40 to 46 percent of genotype 1 patients who undergo an initial 48-week regimen with pegylated-interferon and ribavirin achieve SVR,[2,3,4] or a viral cure. Patients who do not achieve SVR with an initial regimen of pegylated-interferon and ribavirin have a low likelihood of success with re-treatment with pegylated-interferon and ribavirin.[5]

"More than half our patients with genotype 1 infection don't respond to pegylated-interferon and ribavirin, and they have a very limited chance of achieving permanent viral eradication when re-treated using currently approved therapies," said John McHutchison, M.D., Lead Investigator for the PROVE 3 trial and Associate Director of the Duke Clinical Research Institute. "There is, therefore, a clear need for more effective treatment options in these patients. The significantly higher SVR rates observed in the PROVE 3 trial with telaprevir-based regimens represent an important step forward in the potential future treatment of patients who have failed current therapies."

"More than 50 percent of the treatment-failure patients who received telaprevir in combination with pegylated-interferon and ribavirin in the PROVE 3 trial achieved a sustained viral response - a striking result in this difficult-to-treat patient population," said Robert Kauffman, M.D., Ph.D., Senior Vice President, Clinical Development and Chief Medical Officer for Vertex. "Based on the PROVE 3 data, as well as clinical data from the PROVE 1 and PROVE 2 trials in treatment-naïve patients published in the *New England Journal of Medicine* in April 2009, Vertex is currently evaluating telaprevir in a global Phase 3 registration program that enrolled more than 2,200 treatment-failure and treatment-naïve HCV patients. Assuming the trials are successful, we expect to submit an application for approval of telaprevir with the U.S. FDA in the second half of 2010."

PROVE 3 Trial Results

PROVE 3 was a Phase 2b, randomized, partially double-blind, partially placebo-controlled trial that enrolled and treated 453 genotype 1 HCV patients who did not achieve SVR with a previous regimen of pegylated-interferon (peg-IFN) and ribavirin (RBV) therapy. PROVE 3 consisted of three telaprevir-based treatment arms and one control arm. The trial enrolled patients at 53 international clinical trial sites.

The primary endpoint of the PROVE 3 trial was SVR, defined as the proportion of patients who had no detectable hepatitis C virus in their blood (undetectable plasma HCV RNA) 24 weeks after the completion of therapy. Final SVR results from each arm of the PROVE 3 trial are outlined in the table below:

Final PROVE 3 SVR Results	Arm 1: 12 weeks of telaprevir, Peg-IFN & RBV, followed by 12 weeks of only peg-IFN & RBV*	Arm 2: 24 weeks of telaprevir, Peg-IFN & RBV, followed by 24 weeks of only peg-IFN & RBV*	Arm 3: 24 weeks of telaprevir & Peg-IFN (no ribavirin)*	Arm 4: 48-week Control Arm of Peg-IFN & RBV*
Prior Nonresponse[1]	39%	38%	11%	9%
Prior Relapse[2]	69%	76%	42%	20%
Prior Breakthrough[3]	57%	62%	36%	40%
All Patients	**51%**	**53%**	**24%**	**14%**

* Patients in PROVE 3 received 750mg of telaprevir (or placebo) orally every eight hours, based on treatment arm, and a once-weekly 180ug injection of Peginterferon alfa-2a, as well as a 1,000mg or 1,200mg weight-based daily oral dose of ribavirin.

[1] Non-responders are defined as patients who never achieved undetectable HCV RNA during or at the end of prior therapy. In this trial, 260 patients (260 of 453; 57%) were classified as having prior nonresponse to HCV therapy.

[2] Relapsers are defined as patients who achieved undetectable HCV RNA after prior treatment, but relapsed during follow-up and did not achieve SVR. In this trial, 162 patients (162 of 453; 36%) were classified as having prior relapse to HCV therapy.

[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. In this trial, 31 patients (31 of 453; 7%) were classified as having prior breakthrough to HCV therapy.

The SVR rates for the 24-week (arm one) and 48-week (arm two) regimens that included ribavirin were similar. However the relapse rate for the 24-week regimen (arm one) was 30 percent compared to 13 percent in the 48-week regimen (arm two). The relapse rate was 53 percent for the 24-week regimen that did not include ribavirin (arm three) and 53 percent for the control arm.

Together, these data suggest that a 48-week telaprevir-based treatment regimen that includes 12 weeks of telaprevir, pegylated-interferon and ribavirin followed by 36 weeks of only pegylated-interferon and ribavirin may provide treatment-failure patients with an increased likelihood of achieving SVR. A Phase 3 clinical trial known as the REALIZE trial is ongoing in treatment-failure patients, including patients with nonresponse to prior HCV therapy, and is evaluating a 48-week telaprevir-based treatment regimen that contains 12 weeks of telaprevir, pegylated-interferon and ribavirin followed by 36 weeks of only pegylated-interferon and ribavirin.

Patients who did not achieve SVR in the control arm of the PROVE 3 trial, as well as patients who did not achieve SVR in the control arms of the PROVE 1 and PROVE 2 trials, could enroll in Study 107, an open-label rollover trial of telaprevir-based treatment. Results of Study 107 will be presented at the 45th Annual Meeting of the European Association for the Study of the Liver (EASL; The International Liver Congress™) in Vienna, Austria on April 15, 2010.

Telaprevir Safety & Tolerability in PROVE 3

Several of the most common adverse events in PROVE 3, such as fatigue and influenza-like symptoms, were consistent with typical interferon-related adverse events. The most common adverse events reported more frequently in the telaprevir treatment arms compared to the placebo arms were fatigue, pyrexia, gastrointestinal disorders, pruritus, rash, alopecia, insomnia and anemia. Patients who received a telaprevir-based regimen were more likely to discontinue all treatment because of an adverse event (50 of 339 patients; 15 percent overall), as compared to the control arm (5 of 114 patients; 4 percent overall). Skin disorders were the most common cause of discontinuation in the telaprevir arms (22 of 50 the patients who discontinued because of adverse events), with the majority of these patients discontinuing all treatment because of rash. The overall discontinuation rate due to rash in the telaprevir-based arms was 5 percent (18 of 339 patients).

About Telaprevir

Telaprevir is an investigational, oral inhibitor of HCV protease, an enzyme essential for viral replication, and is being evaluated as part of a global Phase 3 registration program in more than 2,200 treatment-naïve and treatment-failure patients. Vertex is collaborating with Tibotec and Mitsubishi Tanabe Pharma to develop telaprevir. Vertex retains commercial rights to telaprevir in

North America. Tibotec has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and other countries. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries.

About Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), which is found in the blood of people with the disease.[6] Chronic HCV infection affects up to 3.9 million individuals in the United States[1] and is spread through direct contact with the blood of infected people.[6] Though many people with HCV infection may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.[6] Chronic HCV can lead to serious liver problems, including liver damage, cirrhosis, liver failure, or liver cancer.[6] The majority of patients infected with HCV were born between 1946 and 1964, accounting for two of every three chronic HCV cases.[7] The majority of patients infected with HCV are unaware of their infection.[1] Over the next 20 years, total annual medical costs for patients with HCV infection are expected to more than double, from $30 billion today to approximately $85 billion.[7]

Current therapies for HCV typically result in a sustained viral response in about half of patients with genotype 1 HCV, the most common strain of the virus.[2,3,4] If treatment is not successful and patients do not achieve an SVR, they remain at risk for progressive liver disease.[8,9,10,11] The risk of liver failure, liver cancer or death following unsuccessful HCV treatment was assessed at 23% after 4 years, and 43% after 8 years.[9]

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, epilepsy, cancer, and pain.

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

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

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Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements, including statements regarding (i) the Phase 3 program for telaprevir nearing completion and the expectation of Phase 3 SVR data being available in second quarter of 2010 for treatment-naïve patients and in third quarter of 2010 for treatment-failure patients, (ii) the planned submission of a New Drug Application for telaprevir in the second half of 2010 in treatment-naïve and treatment-failure HCV patients, (iii) the significantly higher SVR rates observed in the PROVE 3 trial with telaprevir-based treatment regimens representing an important step forward in the potential future treatment of patients who have failed current therapies, (iv) the suggestion that a 48-week telaprevir-based treatment regimen that includes 12 weeks of telaprevir, pegylated-interferon and ribavirin followed by 36 weeks of only pegylated-interferon and ribavirin may provide treatment-failure patients with an increased likelihood of achieving SVR and (v) the planned presentation of results from Study 107 at the 45th Annual Meeting of the European Association for the Study of the Liver. 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 clinical trials) may not be favorable or may be less favorable than the outcomes obtained from earlier studies such as the PROVE 3 trial, that there may be varying interpretations of data produced by one or more of the Company's clinical trials, 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 the Company's product candidates 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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SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated
Media
Zachry Barber, 617-444-6470
or
Amy Pasqua, 617-444-6075
or
Investors
Michael Partridge, 617-444-6108
or
Lora Pike, 617-444-6755

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