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75% of Treatment-Naïve Patients with Chronic Hepatitis C Achieve SVR (Viral Cure) with Telaprevir-Based Treatment in Phase 3 Trial

-Majority of patients treated with telaprevir received a 24-week regimen-
-6.9% and 7.7% treatment discontinuation rates due to adverse events in 12- and 8-week telaprevir-based treatment arms -- lower than previous telaprevir trials-
-First Phase 3 trial results for a direct acting antiviral therapy in hepatitis C-

CAMBRIDGE, Mass., May 25, 2010 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that 75% of people chronically infected with genotype 1 hepatitis C virus (HCV) who had not previously been treated achieved a sustained viral response (SVR or viral cure) after receiving a 12-week telaprevir-based combination regimen, followed by treatment with pegylated-interferon and ribavirin alone, in the Phase 3 ADVANCE trial. 69% of people achieved SVR after receiving an 8-week telaprevir-based combination regimen, followed by treatment with pegylated-interferon and ribavirin alone. 44% of people in the control arm achieved SVR after 48 weeks of treatment with the currently approved regimen of pegylated-interferon and ribavirin.

The safety and tolerability profile of telaprevir in the ADVANCE trial was consistent with the profile reported in Phase 2 studies, with an improvement in treatment discontinuation rates due to adverse events. Adverse events leading to discontinuation of all study drugs occurred in 6.9%, 7.7% and 3.6% of patients in the 12-week telaprevir-based arm, the 8-week telaprevir-based arm and the control arm, respectively.

"These first Phase 3 results are important for people with hepatitis C, as they represent a potential new era of therapy where doctors may be able to use direct acting antiviral medicines to improve treatment and help patients potentially avoid life-threatening liver-related consequences associated with chronic hepatitis C," said Ira Jacobson, M.D., Chief of the Division of Gastroenterology and Hepatology, Weill Cornell Medical College, and an Investigator for the ADVANCE trial. "The ADVANCE results confirm findings seen in earlier trials of telaprevir and highlight that telaprevir-based combination regimens may increase viral eradication rates and shorten treatment time for many patients."

"These groundbreaking data are the result of our more than decade-long commitment to improving care for people with hepatitis C and should provide new hope for patients with this disease," said Robert Kauffman, M.D., Ph.D., Senior Vice President and Chief Medical Officer for Vertex. "As fewer than half of people with genotype 1 hepatitis C achieve a viral cure with currently approved therapies, new and more effective medicines are urgently needed.

"These results for telaprevir show that 75 percent of patients in the 12-week telaprevir arm achieved a viral cure, with the majority receiving only 24 weeks of therapy, marking what we believe may be a potentially dramatic improvement in the future treatment of hepatitis C," concluded Dr. Kauffman.

Telaprevir is an investigational, oral inhibitor of HCV protease, an enzyme essential for viral replication, and is being developed by Vertex Pharmaceuticals in collaboration with Tibotec Pharmaceuticals and Mitsubishi Tanabe Pharma. 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.

About the ADVANCE Trial

ADVANCE was a Phase 3, randomized, double-blind, placebo-controlled trial that enrolled approximately 1,095 people infected with genotype 1 chronic HCV, the most common form of the virus in the U.S. and Europe, who had not previously been treated for their HCV infection. The trial enrolled patients at 114 international clinical trial sites worldwide. Approximately 60% of the patients in ADVANCE were enrolled at trial sites in North America. Additionally, approximately 20% of the patients in ADVANCE were African American, Black, Hispanic or Latino, and approximately 20% had advanced fibrosis or cirrhosis.

The primary endpoint of the ADVANCE trial was SVR defined as the proportion of patients who had undetectable HCV RNA both at the end of treatment and 24 weeks after the end of treatment. The secondary endpoint was to evaluate the safety of telaprevir when dosed in combination with pegylated-interferon and ribavirin.

As part of a response-guided design, patients in the telaprevir-based treatment arms who had undetectable HCV RNA (<25IU/mL and undetectable by Roche COBAS Taqman HCV test) at Week 4 and Week 12 of treatment were eligible to receive 24 total weeks of therapy. Patients who did not meet the response-guided criterion but were undetectable at Week 24 received 48 total weeks of therapy. Patients received 750 mg of telaprevir (or placebo) orally (tablets) every eight hours (q8h), a 180 ug injection of peginterferon alfa-2a (Pegasys) once-weekly, and a 1,000 mg or 1,200 mg weight-based daily oral dose of ribavirin (Copegus).

SVR Results (Intent to Treat Analysis)

Telaprevir-Based Treatment Arm	***SVR Rate***	***Treatment Regimen***
12-week telaprevir-based arm:	75% (p<0.0001)	12 weeks of telaprevir, pegylated-interferon and ribavirin followed by 12 or 36 weeks of only pegylated interferon and ribavirin, based on response to treatment at Week 4 and Week 12
8-week telaprevir-based arm:	69% (p<0.0001)	8 weeks of telaprevir, pegylated-interferon and ribavirin followed by 16 or 40 weeks of only pegylated interferon and ribavirin, based on response to treatment at Week 4 and Week 12
Control arm:	44%	48 weeks of pegylated-interferon and ribavirin

The SVR rates observed in the two telaprevir-based treatment arms were statistically significant when compared to the control arm (p<0.0001).

For patients in the 12-week telaprevir-based arm, the 8-week telaprevir-based arm and the control arm, 68%, 66% and 9%, respectively, had undetectable HCV RNA 4 weeks after the initiation of treatment, defined as a rapid viral response (RVR) by the American Association for the Study of Liver Diseases Practice Guidelines.[1]

Viral Relapse Rates

For patients in the 12-week telaprevir-based treatment arm, the 8-week telaprevir-based treatment arm and the control arm, 8.6%, 9.5% and 28%, respectively, experienced viral relapse (defined as the proportion of patients who achieved undetectable HCV RNA at the completion of all treatment but relapsed during post-treatment follow up).

Safety & Tolerability Results from ADVANCE

The safety and tolerability profile of telaprevir in the ADVANCE trial was consistent with the profile reported in Phase 2 trials of telaprevir, with an improvement in treatment discontinuation rates due to adverse events, including rash and anemia. The most common adverse events reported in the telaprevir arms were fatigue, rash, pruritus, nausea, headache and anemia, of which anemia, rash, pruritus and nausea occurred more frequently in the telaprevir-based treatment arms than in the control arm. The majority of these adverse events were mild to moderate.

Adverse events leading to discontinuation of all study drugs occurred in 6.9%, 7.7% and 3.6% of patients in the 12-week telaprevir-based arm, the 8-week telaprevir-based arm and the control arm, respectively. Discontinuation of all treatment due to rash was 1.4%, 0.5% and 0.0% in the 12-week telaprevir-based arm, the 8-week telaprevir-based arm and the control arm, respectively, while discontinuation due to anemia was 0.8%, 3.3% and 0.6% in the 12-week telaprevir-based arm, the 8-week telaprevir-based arm and the control arm, respectively.

Additional data from the ADVANCE trial will be submitted for presentation at a medical meeting in the second half of 2010.

About the Telaprevir Development Program

To date, more than 2,000 patients with hepatitis C have received telaprevir-based regimens as part of Phase 2 clinical trials and the Phase 3 ADVANCE trial. Together, these trials enrolled both treatment-naïve and treatment-failure HCV patients, including difficult to treat patients such as null responders. The telaprevir clinical development program is the largest conducted to date for any investigational direct-acting antiviral therapy for hepatitis C.

ADVANCE is the first of three clinical trials conducted as part of a global Phase 3 registration program for telaprevir in treatment-naïve and treatment-failure patients with chronic HCV infection. Data from the remaining two clinical trials in the registration program, known as the ILLUMINATE and REALIZE trials, are expected in the third quarter of 2010. ILLUMINATE is evaluating telaprevir-based regimens in approximately 500 treatment-naïve HCV patients. REALIZE is evaluating telaprevir-based regimens in approximately 650 treatment-failure HCV patients.

Telaprevir is being developed by Vertex Pharmaceuticals in collaboration with Tibotec Pharmaceuticals and Mitsubishi Tanabe

Pharma. Vertex retains commercial rights to telaprevir in North America. Tibotec has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain 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.[2] While chronic HCV infection affects up to 3.9 million individuals in the United States, 75% of those infected are unaware of their infection.[3] Approximately 60 percent of genotype 1 patients who undergo an initial 48-week regimen with pegylated-interferon and ribavirin, the currently approved treatment regimen, do not achieve sustained viral response (SVR),[4,5,6] or a virologic cure.[1]

HCV is spread through direct contact with the blood of infected people.[2] Though many people with HCV infection may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.[2] Chronic HCV can lead to serious liver problems, including liver damage, cirrhosis, liver failure, or liver cancer.[2] If treatment is not successful and patients do not achieve an SVR, they remain at risk for progressive liver disease.[7,8,9,10,11] In the United States, HCV infection is the leading cause of liver transplantations and is reported to contribute to 4,600 to 12,000 deaths annually.[8] The majority of patients infected with HCV were born between 1946 and 1964, accounting for two of every three chronic HCV cases.[11] 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.[11]

Additional resources for media, including an HCV backgrounder and glossary of common terms, are available at: http://investors.vrtx.com/press.cfm

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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.

Pegasys and Copegus are registered trademarks of Hofmann-LaRoche.

Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements, including statements regarding (i) the potential importance of the ADVANCE results as described above by Drs. Jacobson and Kauffman, (ii) our plan to submit a New Drug Application for telaprevir in the second half of 2010 for both treatment-naïve and treatment-failure patients, (iii) our plan to submit additional data from ADVANCE for presentation at a medical meeting in the second half of 2010, and (iv) the expected receipt of data from other ongoing Phase 3 trials known as ILLUMINATE and REALIZE in the third quarter of 2010. 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 future outcomes for any of the other 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 trials and Study C208; that there may be varying interpretations of data produced in one or more of the clinical trials of telaprevir; that regulatory authorities will require more extensive data for a telaprevir NDA filing than currently expected; that future scientific, clinical, competitive or other market factors may adversely affect the potential for telaprevir-based combination therapy 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.

Conference Call at 4:30 p.m. ET Today, May 25

Vertex Pharmaceuticals will host a conference call on Tuesday, May 25, 2010 at 4:30 p.m. ET to review recent developments. To listen to the call on the telephone, dial (877) 502-9276 (U.S. and Canada) or (913) 905-1087 (International) and the conference ID number is 8534001. Vertex is also providing a podcast MP3 file available for download on the Vertex website at www.vrtx.com.

The call will be available for replay via telephone commencing May 25, 2010 at 8:00 p.m. ET running through 5:00 p.m. ET on June 1, 2010. The replay phone number for the U.S. and Canada is (888) 203-1112. The international replay number is (719) 457-0820 and the conference ID number is 8534001. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on June 8, 2010.

New York City Investor and Analyst Webcast at 8:00 a.m. ET Tomorrow, May 26

Vertex Pharmaceuticals will also webcast its investor and analyst meeting from New York City on Wednesday, May 26, 2010 at 8:00 a.m. ET.

Both the Tuesday conference call and Wednesday webcast will be broadcast via the Internet at www.vrtx.com. It is suggested that webcast participants go to the web site at least 10 minutes in advance of the call to ensure that they can access the slides. The webcasts are available on the Events & Presentations link on the home page.

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