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More than 80% of Hepatitis C Patients Treated in Study C208 Achieved an SVR with Telaprevir-Based Regimens

- ***83% SVR achieved with twice-daily regimen of telaprevir dosed with PEGASYS and ribavirin***
- ***Results highlight the use of response-guided therapy in managing treatment outcomes***
- ***Similar safety and tolerability observed between telaprevir-based regimens dosed either twice daily or three times daily***

BOSTON, Oct 31, 2009 (BUSINESS WIRE) -- More than 80 percent of hepatitis C patients in each arm of the Phase 2 Study C208 achieved a sustained viral response (SVR) with a telaprevir-based regimen according to results of an intent-to-treat (ITT) analysis announced today by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX). The data from Study C208 will be presented in an oral presidential plenary session at the 60th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which began yesterday in Boston. Telaprevir is a hepatitis C virus (HCV) protease inhibitor being developed by Vertex Pharmaceuticals Incorporated in collaboration with Tibotec and Mitsubishi Tanabe Pharma.

Study C208 explored telaprevir-based regimens dosed either every 12 hours (q12h; twice daily) or every eight hours (q8h; three times daily) combined with either peg-IFN-alfa-2a (PEGASYS(R)) or peg-IFN-alfa-2b (PEGINTRON(R)) and ribavirin (RBV), for 12 weeks followed by an additional 12 weeks of peg-IFN and RBV in a response-guided trial design that included 161 treatment-naïve patients (intent-to-treat analysis) with genotype 1 hepatitis C virus (HCV) infection. Across the four arms, SVR rates were 82 and 83 percent in patients treated with the every 12 hour telaprevir-based regimen (PEGINTRON and PEGASYS, respectively) and 81 and 85 percent in patients treated with the every 8 hour regimen (PEGINTRON and PEGASYS, respectively). For the majority of patients, these SVR rates were obtained with a 24-week telaprevir-based regimen.

"With high SVR rates and similar safety outcomes between the twice-daily and three-times-daily treatment groups, the results from this exploratory study support the future evaluation of telaprevir-based regimens dosed twice daily," said Professor Patrick Marcellin, M.D., from Beaujon Hospital in Clichy, France. "These results also highlight the potential future role for response-guided therapy with the goal of improving treatment outcomes and potentially shortening the duration of therapy for the majority of patients."

Study C208 Results	**RVR***	**SVR****
TVR (q12h/peg-IFN alfa-2a/RBV) (n=40)	83% (n=33)	83% (n=33)
TVR (q12h/peg-IFN alfa-2b/RBV) (n=39)	67% (n=26)	82% (n=32)
TVR (q8h/peg-IFN alfa-2a/RBV) (n=40)	80% (n=32)	85% (n=34)
TVR (q8h/peg-IFN alfa-2b/RBV) (n=42)	69% (n=29)	81% (n=34)

** Rapid Viral Response: Undetectable HCV RNA at week 4*
*** Sustained Viral Response: Undetectable HCV RNA 24 weeks after the end of treatment*
alfa-2a: PEGASYS
alfa-2b: PEGINTRON

About Study C208

Study C208 was an exploratory, four-arm, randomized, open label, Phase 2 clinical trial that was conducted by Tibotec in Europe in 161 treatment-naïve patients with genotype 1 HCV infection. The objective of Study C208 was to explore the safety, efficacy, tolerability and pharmacokinetics of telaprevir administered every 12 hours (1125mg) or every eight hours (750mg). Each dosing regimen of telaprevir was studied in combination with either peg-IFN-alfa-2a (PEGASYS) or peg-IFN-alfa-2b (PEGINTRON) and ribavirin (RBV), the currently approved therapies for chronic HCV infection. The Study C208 results being presented at AASLD represent the first SVR results for response-guided therapy in treatment-naïve patients with telaprevir-based regimens.

The C208 study protocol stipulated that patients who achieved a rapid viral response (RVR) at week 4 and who maintained

undetectable HCV RNA (<*25 IU/mL,* undetectable Roche COBAS TaqMan HCV test)through to week 20, were able to stop all treatment at the 24-week time point and were followed six-months post-treatment to evaluate whether they achieved an SVR. Patients who did not meet the response-guided criterion were assigned to receive a total of 48 weeks of peg-IFN and RBV therapy. Eighteen percent of patients across the treatment arms were required to continue treatment up to week 48. Low rates of viral relapse (defined as patients who achieved undetectable HCV RNA at the completion of treatment, but relapsed during post-treatment follow up) were observed in patients who completed their assigned regimen (3%). Six percent of patients experienced viral breakthrough (defined as a > 1 $\log_{10}$ increase in HCV RNA from nadir, or HCV RNA > 100 IU/mL in patients whose HCV RNA had previously become undetectable) during the telaprevir dosing period, in line with rates reported from previous Phase 2 studies.

The frequency and severity of adverse events (AEs) and the rate of treatment discontinuations were similar to those reported in prior telaprevir trials. The most common adverse events reported in patients in Study C208 were pruritis, nausea, rash, anemia, flu-like illness, fatigue and headache, and were similar overall between the patient groups receiving every 8 hour dosing and those receiving every 12 hour dosing. Serious AEs leading to permanent treatment discontinuation of all drugs occurred in 8 out 161 patients (5%) and were mainly related to rash (3%, 4/161) and anemia (2%, 3/161).

Webcast at 7:00 p.m. ET on Sunday, November 1, 2009

Vertex intends to provide a live webcast of its investor presentation from Boston beginning at 7:00 p.m. ET on Sunday, November 1, 2009. The presentation may be accessed from the 'Events and Presentations' link on the home page of Vertex's website at www.vrtx.com. A replay of the webcast will also be available on the Company's website until November 16, 2009. To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast.

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 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 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. HCV, a serious public health concern affecting 3.2 million individuals in the United States, is spread through direct contact with the blood of infected people.[1] Though many people with HCV infection may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever.[1] Chronic HCV significantly increases a person's risk for developing long-term infection, chronic liver disease, cirrhosis or death.[1]

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

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.

[1]Centers for Disease Control and Prevention. Hepatitis C Fact Sheet: CDC Viral Hepatitis. Available at: http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf. Accessed, September 24, 2009.

[2] Strader DB, Wright T, Thomas DL, Seeff LB, AASLD practice guideline: diagnosis, management and treatment of hepatitis C. Hepatology: 2004(39):1147-1171.

[3]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 results from the C208 exploratory study supporting the future evaluation of telaprevir-based regimens dosed twice-daily and (ii) the results from the C208 study highlighting the potential future role for response-guided therapy with the goal of improving treatment outcomes and potentially shortening the duration of therapy for the majority of patients. 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 exploratory studies such as the C208 study, 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.

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

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