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Vertex Pharmaceuticals and Tibotec Announce Start of Phase 3 'ADVANCE' Study with Telaprevir in Treatment-Naive, Genotype 1 HCV Patients

- First hepatitis C protease inhibitor to begin Phase 3 clinical development - - Trial designed to confirm potential of telaprevir to increase sustained viral response (SVR) rates with 24-week treatment duration -

CAMBRIDGE, Mass., Mar 13, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Tibotec today announced that patient screening has begun in the ADVANCE study, a pivotal Phase 3 clinical study with the hepatitis C virus (HCV) protease inhibitor telaprevir in combination therapy for treatment-naive patients with chronic HCV infection. Telaprevir is the most advanced HCV protease inhibitor in clinical development targeting treatment of hepatitis C, a disease that afflicts more than 3 million people in the United States alone, and 170 million worldwide. The ADVANCE trial will enroll 1,050 treatment-naive genotype 1 HCV patients and will evaluate two 24-week telaprevir-based regimens in comparison to a 48-week control arm. The primary endpoint of the study is sustained viral response (SVR), defined as undetectable HCV RNA (<10 IU/mL) 24 weeks after the completion of treatment. In this study, rapid viral response (RVR) criteria will be used to determine which telaprevir patients can stop all treatment at 24 weeks.

"This is the first Phase 3 study conducted to evaluate whether an investigational medicine for HCV may be able to both increase the rate of sustained viral response and shorten the duration of therapy to 24 weeks in patients with genotype 1 HCV infection compared to current treatment of 48 weeks. This is important given the expectation that approximately 40 to 50 percent of people with genotype 1 HCV who undergo treatment with current therapies achieve SVR," said John McHutchison, M.D., Associate Director, Duke Clinical Research Institute and a principal investigator for the ADVANCE study. "We're interested to see whether this trial will confirm the encouraging results seen thus far in Phase 2 studies of telaprevir. This study is another important step forward in the evaluation of novel medicines for the treatment of HCV."

"Following discussions with the U.S. FDA in January, we have been able to rapidly finalize the Phase 3 pivotal trial protocol and begin patient screening at the first sites," said John Alam, M.D., Executive Vice President, Medicines Development and Chief Medical Officer of Vertex. "The initiation of the ADVANCE trial underscores our commitment to evaluating the potential for telaprevir to address significant unmet medical needs in HCV."

The ADVANCE Study

The ADVANCE study (A New Direction in HCV Care: A Study of Treatment-Naive Hepatitis C Patients with telaprevir) will be conducted at more than 100 centers in the U.S., E.U. and certain other countries. Patient recruitment is being initiated in the U.S., while sites in other countries will start recruitment as national Clinical Trial Applications (CTAs) for each country are approved. The study arms will include:

-- 24 weeks of therapy, with telaprevir dosed at 750 mg every eight hours (q8h) for 12 weeks in combination with standard doses of pegylated interferon alfa-2a (peg-IFN) and ribavirin (RBV) for 12 weeks, then continuing for another 12 weeks with peg-IFN and RBV alone;

-- 24 weeks of therapy, with telaprevir dosed at 750 mg every eight hours (q8h) for 8 weeks in combination with standard doses of peg-IFN and RBV for 8 weeks, then continuing for another 16 weeks with peg-IFN and RBV alone; and

-- A control arm with standard doses of peg-IFN and RBV dosed for 48 weeks.

Patients in both telaprevir arms who achieve RVR, defined in this study as undetectable (less than 10 IU/mL) HCV RNA levels by the end of week 4, and who stay undetectable at week 12 will receive 24 weeks of treatment. Patients in these treatment arms who do not meet these RVR criteria but are undetectable at week 24 will continue on peg-IFN and RBV for a total duration of 48 weeks.

Updates on the status of Vertex and Tibotec's clinical trials of telaprevir are available at www.clinicaltrials.gov.

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. The types of adverse events that have been commonly observed with peg-IFN and RBV were seen across all treatment arms in Phase 2b trials of telaprevir. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea, with rash being the most common reason for treatment discontinuation. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were more common in the telaprevir arms compared to the control arm over the dosing period.

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.

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.

Disclosure: Dr. McHutchison receives research support, as does the Duke Clinical Research Institute, from Vertex, and he has served in an advisory capacity for the company.

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

Safe Harbor Statement

This press release contains forward-looking statements, including statements (i) that the ADVANCE Phase 3 clinical trial will evaluate whether an investigational medicine for HCV may be able to increase the rate of SVR and shorten the duration of therapy to 24 weeks in patients with genotype 1 HCV; (ii) regarding the possibility that the ADVANCE Phase 3 clinical trial will confirm the encouraging results seen thus far in Phase 2 studies of telaprevir; (iii) regarding our commitment to evaluating the potential for telaprevir to address significant unmet medical needs in HCV; (iv) that the ADVANCE clinical trial is a pivotal trial that will enroll 1,050 patients; (v) about the design of the treatment arms and control arm of the ADVANCE clinical trial and the manner in which rapid viral response criteria will be used to determine which telaprevir patients can stop all treatment after 24 weeks; (vi) that the ADVANCE clinical trial is another important step forward in the evaluation of novel medicines for the treatment of HCV and (vii) our expectations regarding the number and location of the sites for the ADVANCE clinical trial and our ability to obtain approval to commence screening in foreign countries. While we believe 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 our ongoing or planned clinical trials and in particular the ADVANCE clinical trial may not be favorable or may not confirm results from earlier clinical trials, that there may be varying interpretations of data produced by one or more of our clinical trials, that enrollment in the ADVANCE clinical trial may be more difficult or slower than we currently anticipate and other risks listed under Risk Factors in our annual report on Form 10-K, which was filed with the Securities and Exchange Commission on February 11, 2008. We disclaim any obligation to update the information contained in this press release as new information becomes available.

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