September 24, 2009

# Vertex Pharmaceuticals Announces Publication of Telaprevir Abstracts for Presentation at the 60th AASLD Meeting

## *Presentations to include SVR results from Study C208 exploring twice-daily telaprevir-based dosing regimen, final PROVE 3 results and additional sub-analysis of PROVE 1 and PROVE 2 in "difficult-to-cure" patients*

CAMBRIDGE, Mass., Sep 24, 2009 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that sustained virologic response (SVR) data from Study C208, which evaluated twice-daily dosing of Vertex's investigational hepatitis C virus (HCV) protease inhibitor telaprevir, 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) taking place Oct. 30 - Nov. 3, 2009 in Boston. Additionally, final results from PROVE 3 will be presented in an oral session at the conference. Results from a pooled analysis of PROVE 1 and PROVE 2 in "difficult-to-cure" patients, which include patients with factors potentially having an effect on SVR rates (viral load, race, age, sex, body mass index, genotype subtype and liver fibrosis stage), will be presented in a poster session.

The C208 presentation at AASLD will include SVR data (defined as undetectable HCV RNA at 24 weeks after completion of treatment) and represents the first SVR data for telaprevir-based regimens as part of a response-guided therapy trial design, similar to that being used in the Phase 3 trials of telaprevir. Study C208 is a 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. Two different dosing regimens of telaprevir (750mg three-times daily or 1125mg twice daily) each were studied in combination with either peg-IFN-alfa-2a (PEGASYS)® or peg-IFN-alfa-2b (PEGINTRON)™ and ribavirin (RBV), the standard therapies for chronic HCV infection.

The abstracts were published today and can be accessed on the AASLD website. In accordance with the AASLD embargo policy, the accepted abstract titles are provided below. Vertex is developing telaprevir in collaboration with Tibotec and Mitsubishi Tanabe Pharma.

**Telaprevir Presentations**

*Twice-daily compared to three-times daily telaprevir-based therapy: Study C208*

1. "Virological Analysis of Patients Receiving Telaprevir Administered q8h or q12h with Peginterferon-Alfa-2a or -Alfa-2b and Ribavirin in Treatment-Naïve Patients with Genotype 1 Hepatitis C: Study C208" (#194) will be presented in an oral presidential plenary session on Nov. 3, 2009 at 8:15 a.m. EST. The authors of the study are Marcellin, Patrick; Forns, Xavier, Goeser, Tobias; Ferenci, Peter; Nevens, Frederik; Carosi, Giampiero; Drenth, Joost P.; De Backer, Koen; van Heeswijk, Rudolf; Luo Donghan; Picchio, Gaston; Beumont-Mauviel, Maria.

*Telaprevir-based therapy in treatment-experienced patients: PROVE 3 Final Analysis*

2. "PROVE 3 Final Results and 1-Year Durability of SVR with Telaprevir-Based Regimen in Hepatitis C Genotype 1-Infected Patients with Prior Non-response, Viral Breakthrough or Relapse to Peginterferon-Alfa-2a/b and Ribavirin Therapy" (#66) will be presented in an oral parallel session on Nov. 1, 2009 at 6:00 p.m. EST. The authors of the study are McHutchison, John G.; Manns, Michael P.; Muir, Andrew J.; Terrault, Norah; Jacobson, Ira M.; Afdhal, Nezam H.; Heathcote, E. Jenny; Zuezem, Stefan; Reesink, Hendrik W.; Bsharat, Mohammad; George, Shelley; Adda, Nathalie; Di Bisceglie, Adrian M.

*Telaprevir-based therapy in "difficult-to-cure" treatment-naïve patients: PROVE 1 & PROVE 2 Pooled Analysis*

3. "Telaprevir, Peginterferon Alfa-2a and Ribavirin Improved Rates of Sustained Virologic Response (SVR) in "Difficult-to-Cure" Patients With Chronic Hepatitis C (CHC): a Pooled Analysis From the PROVE 1 and PROVE 2 Trials" (#1565) will be presented in a poster session on Nov. 3, 2009 at 8:00 a.m. EST. The authors of the study are Everson, Gregory T.; Dusheiko, Geoffrey M.; Ferenci, Peter; Alves, Katia; Bengtsson, Leif; McNair, Lindsay; McHutchison, John G.; Muir, Andrew; Pawlotsky, Jean-Michel; Zeuzem, Stefan.

**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 retains commercial rights to telaprevir in North America. Vertex and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East and other countries. Vertex is collaborating with Mitsubishi Tanabe Pharma to develop and commercialize telaprevir in Japan and certain Far East countries.

**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 3.2 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 less than 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.

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.

[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.

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

(VRTX - GEN)

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