



March 7, 2011

New Data on Telaprevir and VX-222 for the Treatment of Hepatitis C Accepted For Presentation at EASL Annual Meeting

- Complete results from pivotal Phase 3 REALIZE study of telaprevir in people who had not achieved a viral cure (SVR) with currently available medicines -
- First presentation of data from ongoing Phase 2 study evaluating response-guided, 12- and 24-week regimens of telaprevir and VX-222 combined with pegylated-interferon and ribavirin -
- Analyses of the relationship between IL28B genotype status on viral cure rates from two Phase 3 studies -

CAMBRIDGE, Mass., Mar 7, 2011 (BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) announced today that 15 abstracts on the company's medicines in development for hepatitis C, including its protease inhibitor, telaprevir, and polymerase inhibitor, VX-222, were accepted for presentation at the 46th Annual Meeting of the European Association for the Study of the Liver (EASL) in Berlin, Germany, March 30 to April 3, 2011.

Highlights of data presentations include:

- Complete results from the pivotal Phase 3 REALIZE study will be presented for the first time. Topline results from this study, which evaluated telaprevir in combination with pegylated-interferon and ribavirin in people who had not achieved a viral cure (SVR) with currently available medicines, were announced in September 2010.
- The first data from an ongoing Phase 2 study evaluating 12- and 24-week response-guided regimens of telaprevir and VX-222 in combination with pegylated-interferon and ribavirin will be presented during a late-breaker session (Abstract #1363).
- Retrospective analyses of the relationship between IL28B genotype status and rates of viral cure with telaprevir-based combination therapy from the pivotal Phase 3 studies of REALIZE and ADVANCE will also be presented.

The titles of the abstracts related to Vertex's medicines in development for hepatitis C are included below and the complete abstracts are now available through the EASL website at www.easl.eu.

"This is an exciting time for the treatment of hepatitis C and for Vertex," said Robert Kauffman, M.D., Ph.D., Senior Vice President and Chief Medical Officer for Vertex. "At EASL, we will present, for the first time, complete results from the Phase 3 REALIZE study and early findings of a new study evaluating both of our oral medicines in development for hepatitis C, telaprevir and VX-222 in combination with available medicines."

The regulatory applications for the approval of telaprevir have been granted Priority Review by the U.S. Food and Drug Administration (FDA) and Health Canada and accelerated assessment by the European Medicines Agency for the treatment of people chronically infected with genotype 1 hepatitis C virus (HCV). The applications include data from three registrational studies, ADVANCE, ILLUMINATE and REALIZE, which evaluated telaprevir in people with hepatitis C who were new to treatment as well as those who did not achieve a viral cure after treatment with currently available medicines. For complete information on the telaprevir clinical trials or a fact sheet on the trial designs visit: www.vrtx.com/press.cfm.

Oral Presentations

- "REALIZE Trial Final Results: Telaprevir-based Regimen in Genotype 1 Hepatitis C Virus infection in Patients with Prior Null Response, Partial Response or Relapse to Peginterferon/Ribavirin"; March 31, 2011, 4:15 - 4:30 p.m. CET.
- "Subanalyses of the telaprevir lead-in arm in the REALIZE study: response at week 4 is not a substitute for prior null response categorization"; March 31, 2011, 5:00 - 5:15 p.m. CET.
- "Evolution of Treatment-Emergent Resistant Variants in Telaprevir Phase 3 Clinical Trials (ADVANCE, ILLUMINATE,

REALIZE"); March 31, 2011, 5:30 - 5:45 p.m. CET.

- "Similar SVR Rates in IL28B CC, CT or TT Prior Relapsers, Partial- or Null-Responders Patients Treated with Telaprevir/Peginterferon/ Ribavirin: Retrospective Analysis of the REALIZE Study"; March 31, 2011, 6:45 - 7:00 p.m. CET.

Poster Presentations

- Late Breaker #1363: "VX-222 with TVR Alone or in Combination with Peginterferon ALFA-2A and Ribavirin in Treatment-Naïve Patients With Chronic Hepatitis C: ZENITH Study Interim Results"; March 31 — April 2, 2011.
- Late Breaker #1369: "Telaprevir Substantially Improved SVR Rates Across All IL28B Genotypes in ADVANCE Trial"; March 31 — April 2, 2011.
- #451: "Telaprevir in Combination with Peginterferon Alfa-2a and Ribavirin: Analyses of Pre-Defined Subpopulations in the Phase 3 ADVANCE Trial"; March 31, 2011, 1:30 — 2:30 p.m. CET.
- #415: "Telaprevir in Combination with Peginterferon Alfa-2a and Ribavirin Increased Sustained Virologic Response Rates in Treatment-Naïve Patients Regardless of Race or Ethnicity"; March 31, 2011, 1:30 — 2:30 p.m. CET.
- #477: "Anemia Had no Effect on Efficacy Outcomes in Treatment-Naïve Patients who Received Telaprevir-Based Regimen in the ADVANCE and ILLUMINATE Phase 3 Studies"; March 31, 2011, 1:30 — 2:30 p.m. CET.
- #400: "Modeling, Clinical and Virology Data From Phase 2 and 3 Studies Support 12-week Telaprevir Duration In Combination with 24- or 48-week Peginterferon/Ribavirin Duration"; March 31, 2011, 1:30 — 2:30 p.m. CET.
- #1202: "Characterization of HCV Variants in Non-SVR Patients in the REALIZE Study Suggests that Telaprevir Exhibits a Consistent resistance profile Irrespective of a Lead-in", April 2, 2011, 12:30 — 1:30 p.m. CET.
- #1244: "The Pharmacokinetic Interaction between Methadone and the Investigational HCV Protease Inhibitor Telaprevir"; April 2, 2011, 12:30 — 1:30 p.m. CET.
- #1245: "The Effect of Severe Renal Impairment on the Pharmacokinetics of the Investigational HCV Protease Inhibitor Telaprevir"; April 2, 2011, 12:30 — 1:30 p.m. CET.
- #1208: "Impact of Telaprevir-based Treatment Regimens on Fatigue in Genotype 1 HCV Treatment-naïve Patients: Results from ADVANCE and ILLUMINATE Studies"; April 2, 2011, 12:30 — 1:30 p.m. CET.
- #1242: "Long-term Follow-up of Chronic Hepatitis C Infected Patients Treated with Telaprevir: Evaluation of Persistence of Resistant Variants by Ultra-deep Sequencing"; April 2, 2011, 12:30 — 1:30 p.m. CET.

About Telaprevir and VX-222

Vertex has two oral medicines in late-stage development for the treatment of hepatitis C: telaprevir and VX-222. Telaprevir is an investigational, oral inhibitor that acts directly on the HCV protease, an enzyme essential for viral replication. To date, more than 2,500 people with genotype 1 hepatitis C have received telaprevir in Phase 2 and Phase 3 studies. Vertex has received priority review for its applications for the approval of telaprevir by the U.S. FDA and Health Canada.

Vertex is developing telaprevir in collaboration with Tibotec BVBA and Mitsubishi Tanabe Pharma. Vertex has rights to commercialize telaprevir in North America. Through its affiliate, Janssen, 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.

VX-222 is an investigational, oral, non-nucleoside inhibitor of HCV NS5B polymerase. VX-222 is currently being evaluated in combination with telaprevir, pegylated-interferon and ribavirin in a Phase 2 study. Vertex has worldwide commercial rights for VX-222.

About Hepatitis C

Hepatitis C is a serious liver disease caused by the hepatitis C virus, which is spread through direct contact with the blood of infected people and ultimately affects the liver.¹ Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer.¹ Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.¹ Approximately 60 percent of genotype 1 hepatitis C patients who undergo treatment with an initial 48-week regimen with pegylated-interferon and ribavirin, the currently approved medicines, do not achieve SVR,^{2,3,4} or viral cure.⁵ If treatment is not successful and a person does not achieve a viral cure, they remain at an increased risk for progressive liver disease.^{6,7,8,9,10}

More than 170 million people worldwide are chronically infected with hepatitis C. In the United States, up to 3.9 million people have chronic hepatitis C and of those, 75 percent are unaware of their infection.¹¹ The majority of people with hepatitis C in the United States were born between 1946 and 1964, accounting for two of every three people with chronic hepatitis C.¹⁰ Hepatitis C is the leading cause of liver transplantations in the United States and is reported to contribute to 4,600 to 12,000 deaths annually.⁷ By 2029, total annual medical costs in the United States for people with hepatitis C are expected to more than double, from \$30 billion in 2009 to approximately \$85 billion.¹⁰

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Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements regarding the data from clinical trials involving telaprevir and/or VX-222 that Vertex expects to feature in poster and oral presentations at EASL, March 30 to April 3, 2011. While Vertex believes these data will be presented at EASL, it is possible that future developments could adversely affect the content, timing or form of those presentations.

About Vertex

Vertex creates new possibilities in medicine. Our team aims to discover, develop and commercialize innovative therapies so people with serious diseases can lead better lives.

Vertex scientists and our collaborators are working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, MA, we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada.

For more information and to view Vertex's press releases, please visit www.vrtx.com.

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References:

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³ Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. *N Engl J Med*. 2002;347:975-982.

⁴ McHutchison JG, Lawitz EJ, Shiffman ML, et al; IDEAL Study Team. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. *N Engl J Med*. 2009;361:580-593.

⁵ Ghany MG, Strader DB, Thomas DL, Seeff, LB. Diagnosis, management and treatment of hepatitis C; An update. *Hepatology*. 2009;49 (4):1-40.

⁶ Morgan TR, Ghany MG, Kim HY, Snow KK, Lindsay K, Lok AS. Outcome of sustained virological responders and non-responders in the Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) trial. *Hepatology*. 2008;50(Suppl 4):357A (Abstract 115).

⁷ Davis GL, Alter MJ, El-Serag H, Poynard T, Jennings LW. Aging of hepatitis C virus (HCV)-infected persons in the United States: A multiple cohort model of HCV prevalence and disease progression. *Gastroenterology*. 2010;138:513-521.

⁸ Volk MI, Tocco R, Saini S, Lok, ASF. Public health impact of antiviral therapy for hepatitis C in the United States. *Hepatology*. 2009;50(6):1750-1755.

⁹ Veldt BJ, Heathcote J, Wedmeyer H. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. *Annals of Internal Medicine*. 2007; 147: 677-684.

¹⁰ Pyenson B, Fitch K, Iwasaki K. Consequences of hepatitis C virus (HCV): Costs of a baby boomer epidemic of liver disease. http://www.natap.org/2009/HCV/051809_01.htm. Updated May 2009. *This report was commissioned by Vertex Pharmaceuticals, Inc.*

¹¹ Institute of Medicine of the National Academies. Hepatitis and liver cancer: a national strategy for prevention and control of hepatitis B and C. Colvin HM and Mitchell AE, ed. <http://www.iom.edu/Reports/2010/Hepatitis-and-Liver-Cancer-A-National-Strategy-for-Prevention-and-Control-of-Hepatitis-B-and-C.aspx>. Updated January 11, 2010. Accessed May 25, 2010.

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Source: Vertex Pharmaceuticals

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