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# Vertex Announces Publication of Abstracts for Presentation at 58th AASLD Meeting

# -- Conference Presentations to Include Data from Two Randomized, Controlled Phase 2 Clinical Studies of Investigational HCV Protease Inhibitor Telaprevir --

CAMBRIDGE, Mass., Sep 28, 2007 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that 6 abstracts related to its investigational hepatitis C protease inhibitor telaprevir have been accepted for presentation at the 58th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), November 2-6, 2007, and are being published online by the AASLD. Included in these abstracts are planned presentations of interim data from PROVE 1 and PROVE 2, two randomized, controlled Phase 2 studies of telaprevir. Vertex is developing telaprevir in collaboration with Tibotec.

At the AASLD conference, Vertex expects that researchers will present the most recent antiviral and safety data that are available from PROVE 1 and PROVE 2. Data from PROVE 1 and PROVE 2 being presented at AASLD represent interim analyses, and Vertex continues to gather information on the safety and antiviral effect of telaprevir-based therapy to determine the appropriate regimens and durations for evaluation in further studies. An overview of PROVE 1 and PROVE 2 clinical studies, expected data available, and abstract title and presentation time information are provided below.

PROVE 1 (Study 104)

PROVE 1 is an ongoing, four-arm, 250-patient Phase 2 study whose primary objective is to assess the proportion of patients who achieve sustained viral response (SVR), defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan (R) assay) HCV RNA 24 weeks after the completion of dosing. The study is assessing patients who receive telaprevir-based treatment durations of 12, 24 and 48 weeks, compared to a 48-week control arm of Peg-IFN+RBV. PROVE 1 is being conducted at more than 30 clinical centers in the U.S.

Key interim data expected to be available at AASLD include:

-- 24-week post-treatment (SVR24) data from patients from the "12+12" arm, who received telaprevir dosed in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) for 12 weeks, followed by 12 weeks with peg-IFN and RBV alone (arm C of PROVE 1)

-- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks only (arm D of PROVE 1)

-- End of treatment data from patients from the "12+36" arm, who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks, followed by 36 weeks with peg-IFN and RBV alone (arm B of PROVE 1)

-- End of treatment data from patients from the control arm, who received 48 weeks of therapy with peg-IFN and RBV only (arm A of PROVE 1)

-- Available data on safety and tolerability across all arms of the study, including characterization of the most commonly observed adverse events, and identification of the adverse events that led to treatment discontinuation.

PROVE 1 data will be presented on Tuesday, November 6, 2007. The abstract is titled "Interim Analysis Results from a Phase II Study of Telaprevir with Peg-interferon alfa-2a and Ribavirin in Treatment-naive Subjects with Hepatitis C," and the authors are I. M. Jacobson, G. T. Everson, S. C. Gordon, R. Kauffman, L. McNair, A. Muir, and J. G. McHutchison.

# PROVE 2 (Study 104EU)

PROVE 2 is a four-arm Phase 2 study of approximately 320 patients whose primary objective is to assess the proportion of patients who achieve SVR. The study assesses patients who receive telaprevir-based treatment durations of 12, 24 and 48 weeks, compared to a 48-week control arm. PROVE 2 is being conducted at more than 40 clinical centers in Europe.

Key interim data expected to be presented at AASLD include:

-- 12 week post-treatment (SVR12) data from patients in the "12+12" arm (arm B of PROVE 2)

-- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN and RBV for 12 weeks only (arm C of PROVE 2)

-- 24-week post-treatment (SVR24) data from patients who received telaprevir dosed in combination with peg-IFN for 12 weeks only, without RBV (arm D of PROVE 2)

-- Available on-treatment data for patients in the control arm, who received 48 weeks of therapy with peg-IFN and RBV (arm A of PROVE 2).

-- Available data on safety and tolerability across all arms of the study, including characterization of the most commonly observed adverse events, and identification of the adverse events that led to treatment discontinuation.

PROVE 2 data will be presented on Monday, November 5, 2007. The abstract is titled "PROVE 2: Phase II Study of VX-950 (Telaprevir) in Combination with Peginterferon alfa-2a with or without Ribavirin in Subjects with Chronic Hepatitis C, First Interim Analysis," and the authors are C. Hezode, P. Ferenci, G. M. Dusheiko, S. Pol, T. Goeser, J. Bronowicki, S. Gharakhanian, D. Devonish, R. Kauffman, J. Alam, J. Pawlotsky, and S. Zeuzem.

### Additional Telaprevir Abstracts at AASLD

In addition to those abstracts for PROVE 1 and PROVE 2, four abstracts related to the telaprevir development program were accepted for presentation at AASLD. These are listed below.

"Final Results of Patients Treated with Peg-interferon alfa-2a (Peg-IFN) and Ribavirin (RBV) Follow-on Therapy After 28-day Treatment with Hepatitis C Protease Inhibitor Telaprevir (VX-950), Peg-IFN and RBV," M. Rodriguez-Torres, E. J. Lawitz, J. G. McHutchison, Tuesday, November 6, 2007, 11:15am (Abstract 175).

Patients in this exploratory Phase 2a study received 28 days of telaprevir dosed in combination with peg-IFN and RBV, and subsequently received post-study therapy with peg-IFN and RBV through a total of 48 weeks of treatment. 24-week post-treatment (SVR24) data will be presented.

"Final Results of Patients Receiving Peg-interferon alfa-2a (peg-IFN) and Ribavirin (RBV) After a 14-day Study of the Hepatitis C Protease Inhibitor Telaprevir (VX-950) with peg-IFN," C. J. Weegink, N. Forestier, P. L. Jansen, S. Zeuzem, H. W. Reesink, Tuesday, November 6, 2007, 8:00am-12:30pm (Abstract 1309).

Patients in this exploratory Phase 1b study received 14 days of telaprevir dosed either alone or in combination with peg-IFN, or 14 days of peg-IFN alone, and subsequently received post-study therapy with peg-IFN and RBV through 24 or 48 weeks. 24-week post-treatment (SVR24) data will be presented.

"Evaluation of Viral Variants During a Phase 2 Study (PROVE2) of Telaprevir with Peginterferon alfa-2A and Ribavirin in Treatment-naive HCV Genotype 1-Infected Patients," T. Kieffer, Y. Zhou, E. Zhang, M. Marcial, R. Byrn, T. Pfeiffer, J. Miller, A. Tigges, D. Bartels, A. Kwong, P. Ferenci, G. Dusheiko, S. Zeuzem, J. Pawlotsky, Tuesday, November 6, 2007, 8:00am-12:30pm (Abstract LB8).

Data will be presented characterizing viral variants isolated from patients participating in the PROVE 2 study.

"Telaprevir Resistance Mutations in Patients with Hepatitis C who Relapsed After Sequential Therapy with Telaprevir, Peginterferon alfa 2a and Ribavirin," N. Forestier, S. Susser, M. W. Welker, C. J. Weegink, H. W. Reesink, S. Zeuzem, C. Sarrazin, Sunday, November 4, 2007, 5:00pm (Abstract 50).

Data will be presented characterizing viral variants isolated from patients who participated in the study described in abstract 1309 listed above.

#### About Telaprevir (VX-950)

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 agents in development that specifically targets HCV. Vertex is conducting a global Phase 2b clinical development program for telaprevir consisting of three large clinical trials that has enrolled more than 1,000 patients with HCV at clinical centers in the U.S., Canada and E.U. In these clinical trials, telaprevir is being dosed as 750 mg every 8

hours in combination with peginterferon alfa-2a (Pegasys(R)), both with and without ribavirin (Copegus(R)). Data from PROVE 1 and PROVE 2 being presented at AASLD represent interim analyses, and Vertex continues to gather information on the safety and antiviral effect of telaprevir-based therapy to determine the appropriate regimens and durations for evaluation in further studies.

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 Pharma to develop and commercialize telaprevir in Japan and certain Far East countries.

#### 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.

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

# Special Note Regarding Forward-looking Statements

This press release contains forward-looking statements, including statements regarding our expectation that certain clinical data from the Company's ongoing PROVE 1 and PROVE 2 clinical trials will be available for disclosure at the AASLD conference. While we believe this forward-looking statement to be accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by this forward-looking statement. Those risks and uncertainties include, among other things, that the outcomes for each of the referenced ongoing clinical trials may not be available within expected timelines, for technical or scientific reasons. We disclaim any obligation to update the information contained in this press release as new data become available.

Vertex's press releases are available at <u>www.vrtx.com</u>.

# (VRTX-GEN)

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