

June 12, 2007

# **Vertex Pharmaceuticals Reports 2007 Pipeline Progress**

-- More than 1000 patients have now been enrolled in Phase 2b PROVE trials -- More than 350 patients have completed 12 weeks of telaprevir dosing in PROVE trials -- Interim results from PROVE 2 consistent with findings from PROVE 1

CAMBRIDGE, Mass., Jun 12, 2007 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today detailed recent progress in its clinical pipeline in conjunction with its participation at the Goldman Sachs 28th Annual Healthcare Conference. A live webcast of Vertex's presentation will be available on Vertex's website, <a href="https://www.vrtx.com">www.vrtx.com</a>, beginning at 2:00 p.m. PDT (5:00 p.m. EDT) on June 13, 2007.

"In the first half of 2007, we have made significant progress in advancing our business and in the development of our pipeline," said Joshua Boger, Ph.D., Vertex's President and Chief Executive Officer. "Specifically, we have enrolled more than 1,000 patients in the PROVE studies evaluating telaprevir, our investigational hepatitis C protease inhibitor, and more than 350 patients have now completed 12 weeks of telaprevir-based dosing. Today, we announced the completion of enrollment in PROVE 3. We are now focused on discussions with regulatory agencies in the U.S. and Europe to enable transitioning to the start of Phase 3 development of telaprevir planned for the fourth quarter of this year."

## Mid-2007 Pipeline Update

Broad clinical development program for telaprevir (VX-950)

- -- The PROVE clinical program, consisting of three major Phase 2b trials, is designed to evaluate: 1) the optimal SVR (sustained viral response) rate that can be achieved with telaprevir-based therapy; 2) the optimal treatment duration for telaprevir; 3) the safety profile of telaprevir; and 4) the role of ribavirin in telaprevir-based therapy. In its program for treatment-naive patients, Vertex is focused on evaluating regimens of 24 weeks total duration, with the inclusion of ribavirin in the treatment combination.
  - -- The PROVE 1 clinical trial is continuing on track in the U.S. PROVE 1 is a randomized, placebo-controlled trial that enrolled 250 treatment-naive genotype 1 patients with hepatitis C. Vertex anticipates completing a planned interim analysis in July 2007 for patients in the 24-week treatment arm of this trial. The interim analysis will focus on 12-week post-treatment antiviral results, and Vertex expects that these data will be presented at a medical meeting later in 2007.
- The PROVE 2 clinical trial is also continuing on track in Europe. PROVE 2 is a randomized, placebo-controlled trial that enrolled approximately 240 genotype 1 treatment-naive HCV patients on telaprevir-based regimens and 80 patients who were randomized to receive pegylated interferon alfa 2a (peg-IFN) and ribavirin (RBV). Vertex recently received preliminary data from the first planned interim analysis of PROVE 2, and expects that these data will be presented at a medical meeting later in 2007. At this time, Vertex is reporting that the preliminary results are consistent with findings reported for PROVE 1. Patients in the treatment arms that included telaprevir, peg-IFN and RBV had rates of undetectable HCV RNA (10 IU/mL)

at 4 and 12 weeks similar to those observed in PROVE 1. The adverse events observed in the PROVE 2 trial, and the rate of treatment discontinuations for 240 patients through 12 weeks of telaprevir-based dosing, appear consistent with the PROVE 1 results reported by Vertex in April. At 12 weeks, the treatment arm in PROVE 2 that did not include ribavirin was associated with antiviral activity that was lower compared to treatment arms that included ribavirin, telaprevir, and peg-IFN, but still substantially higher than that observed in the control arm. As reported for PROVE 1, rash, gastrointestinal events and anemia were the most common events leading to discontinuation in the telaprevir arms. Fewer discontinuations due to adverse events were observed in patients receiving telaprevir and peg-IFN without ribavirin.

- -- Vertex today announced that it has completed patient enrollment in the PROVE 3 clinical trial with more than 440 patients. PROVE 3 is a Phase 2b clinical trial of telaprevir in patients with genotype-1 HCV who have not achieved SVR with a previous interferon-based treatment.
- -- With the completion of enrollment in PROVE 3, there are more than 1,000 patients enrolled in the PROVE clinical program for telaprevir and, to date, more than 350 patients who have completed 12 weeks of telaprevir-based dosing.
- -- Vertex and Tibotec, with whom Vertex is collaborating to develop and commercialize telaprevir in Europe and other countries, are using available data on telaprevir to design a comprehensive Phase 3 clinical trial program for telaprevir. Pending additional data from the PROVE program, and the outcome of discussions with regulatory agencies, the start of an international Phase 3 clinical trial for telaprevir in genotype 1 treatment-naive patients is planned for the fourth quarter of 2007.
- -- In May, Vertex successfully completed drug substance registration batches of telaprevir. The Company has also started the manufacturing validation process for telaprevir drug substance and expects to complete the validation by the end of the year. Vertex continues to make a significant investment to prepare for the commercial supply and marketing of telaprevir, subject to its continued progress.
- -- VX-770 in Phase 2 development in cystic fibrosis (CF)
  - -- In the second quarter, Vertex initiated a Phase 2a clinical trial with VX-770. The randomized, double-blind, placebo-controlled trial of VX-770 will evaluate the safety, pharmacokinetics and certain biomarkers of CFTR activity in approximately 35 CF patients with genotype G551D.
- -- MK-0457 (VX-680) Phase 2 trial underway in certain treatment-resistant leukemias
  - -- Vertex's collaborator Merck is conducting a 270-patient Phase 2 clinical trial with MK-0457 in patients with treatment-resistant chronic myelogenous leukemia (CML) and Philadelphia chromosome-positive acute lymphocytic leukemia (PH+ ALL) containing the T315I BCR-ABL mutation. Enrollment is

underway for this study at 12 clinical centers in the U.S., Europe, the Middle East and Asia.

- -- Early-stage compounds
  - -- Vertex has commenced preclinical activities with several novel compounds now emerging from its drug discovery operations. Vertex expects to initiate clinical trials of these compounds by the end of 2007.

## Webcast:

Vertex Pharmaceuticals will webcast its corporate presentation at the Goldman Sachs Healthcare Conference on June 13, 2007 at 2:00 p.m. PDT (5:00 p.m. EDT). A link to the live webcast will be available via Vertex's website, <a href="www.vrtx.com">www.vrtx.com</a>, in the Investor Center. An archived webcast of the presentation will be available on Vertex's website through June 27, 2007.

## **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.

## Safe Harbor Statement

This press release may contain forward-looking statements, including statements concerning (i) our expectations regarding clinical trials, development timelines and discussions with regulatory authorities related to telaprevir and other drug candidates currently under development by us and our collaborators or planned for development; (ii) our expectations about the number of patients that will be evaluated and the data that will be generated by ongoing and planned clinical trials of telaprevir, and the ability to use that data for the design and initiation of further clinical trials; (iii) our expectations regarding the scope and timing of ongoing and potential future clinical trials, including the ongoing Phase 2b clinical trials and expected Phase 3 clinical program for telaprevir, the planned Phase 2a clinical trial of VX-770 and the ongoing clinical trials of MK-0457 (VX-680); (iv) our expectations regarding the progress of our manufacturing activities for telaprevir; and (v) our expectation that final analysis of PROVE 2 results will be consistent with PROVE 1. 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 planned clinical trials and studies, and in particular our planned clinical trials of telaprevir, may not be favorable, that one or more of our internal or external drug development programs will not proceed as planned for technical, scientific or commercial reasons, and other risks listed under Risk Factors in Vertex's annual report and guarterly reports filed with the Securities and Exchange Commission and available through our website at www.vrtx.com. 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 www.vrtx.com.

(VRTX-GEN)

SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated Lynne H. Brum, 617-444-6614 Vice President, Strategic Communications or Michael Partridge, 617-444-6108 Director, Corporate Communications or Lora Pike, 617-444-6755 Manager, Investor Relations or Zachry Barber, 617-444-6470 Senior Media Relations Specialist

Copyright Business Wire 2007

News Provided by COMTEX