



January 7, 2008

Vertex Pharmaceuticals Reports Progress in Development of Investigational HCV Drug Telaprevir and Provides Business Update

- Formal European scientific advice obtained for telaprevir development program - - Meeting scheduled with FDA for January 2008 on Phase 3 trial design and recent data - - Next-generation HCV protease inhibitor and two investigational compounds for cystic fibrosis in clinical development -

CAMBRIDGE, Mass., Jan 07, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced its key business objectives for 2008 and provided an overview of recent developments, including highlights from research and development programs, in conjunction with the 26th Annual JPMorgan Healthcare Conference in San Francisco. At the conference, Joshua Boger, Ph.D., President and Chief Executive Officer, and Kurt Graves, Executive Vice President, Chief Commercial Officer and Head, Strategic Development, will today review Vertex's HCV product development and commercialization strategy. A live webcast of this presentation will be available on Vertex's website, www.vrtx.com, today at 2:00 p.m. PST (5:00 p.m. EST).

"As we enter 2008, Vertex is focused on initiating a Phase 3 clinical program for telaprevir, our lead investigational hepatitis C protease inhibitor," stated Dr. Boger. "Clinical data generated in 2007 has provided a platform for constructive dialogue with U.S. and E.U. regulatory authorities, and in early 2008 we look forward to completing these discussions and advancing telaprevir into pivotal clinical development."

Dr. Boger continued, "As we advance toward the initiation of a Phase 3 development program for telaprevir, and with the expansion of our investigational HCV portfolio to include next-generation protease inhibitors, we believe we will be well-positioned to establish leadership in the HCV treatment landscape."

Telaprevir Regulatory Update for Treatment-Naive Genotype 1 Patients

-- In collaboration with Vertex, Tibotec is developing and commercializing telaprevir in Europe, South America, Australia, the Middle East and other countries. Tibotec has obtained formal scientific advice from European regulatory authorities on the telaprevir development program. Following receipt of this formal scientific advice, Vertex has submitted a Phase 3 protocol to the U.S. Food and Drug Administration (FDA) for review. The submitted Phase 3 trial design includes a 48-week control arm and both 8 and 12 weeks of telaprevir treatment as part of 24-week combination treatment regimens. The Company plans to use rapid viral response (RVR) criteria to determine which patients stop all treatment at 24 weeks.

-- Vertex plans to review this Phase 3 clinical trial design, as well as recently submitted clinical data, at a scheduled meeting with the FDA in January 2008. Tibotec is also in the process of finalizing Phase 3 development plans in Europe. Vertex expects to provide an update on its discussions with the FDA no later than February 11, 2008, the planned date of its year-end financial results conference call.

Telaprevir Clinical Development Plans for Treatment-Failure Genotype 1 Patients

-- Vertex is conducting PROVE 3, a Phase 2b clinical trial of telaprevir-based combination therapy in patients with genotype 1 HCV who have not achieved a sustained viral response (SVR) with a previous pegylated interferon-based treatment. Vertex plans to discuss with regulatory authorities in mid-2008 the next steps in the telaprevir development program for treatment-failure HCV patients after the first interim clinical data are available from the PROVE 3 clinical trial.

Tibotec Leading Two Clinical Trials of Telaprevir in Europe

-- Tibotec initiated in late 2007 a Phase 2 clinical study in Europe to evaluate 8-hourly and 12-hourly dosing of telaprevir in combination with pegylated interferon (Pegasys(R) or Peginteron(R)) and ribavirin. Patients are currently being dosed in this trial. Interim 12-week on-treatment data are expected to be available in the second half of 2008.

-- Tibotec is also conducting a Phase 2 viral kinetics study in Europe to evaluate telaprevir in patients infected with genotype 2/3 HCV. Patients are currently being screened in this trial, and interim on-treatment data are expected to be available in late

2008.

Additional Telaprevir Research Conducted in 2008

-- Also in 2008, Vertex intends to initiate clinical exploration of telaprevir in combination with other investigational HCV therapies.

Next-Generation HCV Protease Inhibitor Program

-- Vertex has initiated dosing in a Phase 1a clinical trial of VX-500, a second-generation investigational HCV protease inhibitor. The trial will evaluate single, escalating doses of VX-500 in healthy volunteers.

-- Pending results from the Phase 1a trial, Vertex expects to initiate in mid-2008 a Phase 1b trial of VX-500 in HCV patients.

-- Vertex expects at least one additional next-generation investigational HCV protease inhibitor to advance from research and enter clinical development in 2008.

"In addition to investigational therapies aimed at hepatitis C, Vertex is also pursuing development of multiple novel compounds for the treatment of other serious diseases," continued Dr. Boger. "Two novel compounds targeting the underlying mechanisms of cystic fibrosis are currently being studied in clinical trials, and we are seeking to advance additional molecules for the treatment of cancer, autoimmune disorders and other significant diseases."

Broad Program Targeting Cystic Fibrosis (CF)

-- Vertex is conducting a randomized, double-blind, placebo-controlled Phase 2a trial of VX-770, an investigational potentiator compound for the treatment of CF. In the trial, VX-770 is being dosed as an oral therapy in patients with CF. Pending results from the Phase 2a trial, Vertex plans to advance VX-770 into a larger Phase 2b trial.

-- Vertex has also initiated dosing in a Phase 1a trial for VX-809, an investigational corrector compound for the treatment of CF. The trial will evaluate single and multiple doses of VX-809 in healthy volunteers. Pending results from the Phase 1a trial, Vertex expects to initiate a subsequent Phase 1b trial in patients with CF in mid-2008.

Productivity in Research

-- Vertex has commenced preclinical activities for a number of additional investigational compounds that are advancing from research and may enter clinical development in 2008.

Vertex will report full-year 2007 financial results and financial guidance for 2008 on February 11, 2008.

Webcast:

Vertex Pharmaceuticals will webcast its corporate presentation at the 26th Annual JPMorgan Healthcare Conference on January 7, 2008 at 2:00 p.m. PST (5:00 p.m. EST). A link to the live webcast will be available via Vertex's website, www.vrtx.com, in the Events & Presentations section. An archived webcast of the presentation will be available on Vertex's website through January 21, 2008.

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 that (i) we look forward to completing U.S. and E.U. regulatory discussions and advancing telaprevir into pivotal clinical development in early 2008; (ii) with our planned initiation of a Phase 3 program for telaprevir and expansion of our investigational portfolio with next-generation HCV protease inhibitors, we believe we are well-positioned to establish leadership in the HCV treatment landscape; (iii) we plan to review a

proposed Phase 3 clinical trial design with the FDA in January 2008 and provide an update on those discussions no later than February 11, 2008; (iv) we plan to discuss with regulatory authorities in mid-2008 the next steps in the development program for telaprevir in treatment-failure patients after the first interim data from the PROVE 3 clinical trial are available; (v) we expect that interim data will be available in the second half of 2008 from a Phase 2 BID clinical trial being conducted by Tibotec, and that interim data will be available in late 2008 from a genotype 2/3 trial of telaprevir being conducted by Tibotec; (vi) we intend to initiate clinical exploration of telaprevir in combination with other investigational HCV therapies in 2008; (vii) we expect to initiate a Phase 1b trial of VX-500 in mid-2008, depending on results from an ongoing Phase 1a trial, and we expect that we will bring at least one additional second-generation HCV protease inhibitor into clinical development in 2008; and (viii) we expect to initiate a Phase 1b trial of VX-809 in CF patients in mid-2008, depending on results from the ongoing Phase 1a trial. While management makes its best efforts to be accurate in making forward-looking statements, such statements are subject to risks and uncertainties that could cause the actual results of studies to vary materially. Those risks and uncertainties include, among other things, the risk that the FDA or other regulatory authorities will not endorse our proposed clinical trial designs, will require substantially altered trial designs or will require more clinical or nonclinical studies before permitting our proposed studies to continue toward regulatory submission and approval, that observed outcomes in clinical investigations of smaller numbers of patients will not be reflected in future clinical trials involving larger numbers of patients, that unexpected and adverse outcomes in ongoing clinical and nonclinical studies will occur and could result in substantial program delays or program terminations, that delays in planning, patient enrollment, drug supply, data collection or analysis or other activities will delay the availability of data from ongoing or planned studies, that planned meetings or discussions with the FDA or other regulatory authorities will be delayed due to scheduling issues, data availability or for other reasons outside the control of the company; that unexpected adverse results from an ongoing clinical trial will adversely impact the occurrence or timing of other planned studies or activities; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 1, 2007. Vertex disclaims any obligation to update the information contained in this press release as new data become available.

(VRTX-GEN)

SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated
Michael Partridge, 617-444-6108
Senior Director, Strategic Communications
or
Lora Pike, 617-444-6755
Manager, Investor Relations
or
Zachry Barber, 617-444-6470
Senior Media Relations Specialist

Copyright Business Wire 2008

News Provided by COMTEX