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Vertex Pharmaceuticals Reports Data on Investigational Hepatitis C Therapies Suggesting Potential for Novel Treatment Approaches

Berlin, Germany, April 16, 2004 -- New data for proprietary investigational antiviral therapies for hepatitis C virus (HCV) infection being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) were presented today at the Annual Meeting for the European Association for the Study of the Liver (EASL) in Berlin, Germany. The clinical and preclinical data presented highlight the potential of these therapies to address significant unmet medical needs in the treatment of HCV.

Vertex's extensive drug development portfolio includes two different approaches for advancing the future standard-of-care in HCV. Merimepodib, Vertex's lead oral therapy targeting HCV, is being developed in combination with the current therapeutic standard, pegylated interferon alpha (peg-IFN) and ribavirin, with the goal of enhancing antiviral efficacy and increasing the proportion of patients who achieve a sustained response to treatment. Vertex is also developing VX-950, an investigational HCV protease inhibitor and one of the most advanced of a new class of direct antiviral agents for the treatment of chronic HCV infection. Vertex owns worldwide development and commercialization rights for both merimepodib and VX-950.

In a poster session at EASL today, clinical investigators presented results for patients enrolled in the extension phase of a pilot Phase IIa study designed to evaluate the safety and tolerability of merimepodib in combination with peg-IFN and ribavirin in a treatment-refractory population. Additionally, in oral presentations at EASL, Vertex scientists reported preclinical data highlighting the promising antiviral profile of VX-950, including in vitro data assessing the antiviral activity of VX-950 in combination with interferon alpha.

"The results presented at EASL provide strong support for initiating late-stage clinical development of merimepodib, as well as the first clinical studies of VX-950," stated John Alam, M.D., Senior Vice President for Drug Evaluation and Approval at Vertex. "These are key milestones for Vertex and its interest in providing new therapies in HCV, and are anticipated in 2004. Vertex's goal is to commercialize innovative therapies that will provide additional options for patients and enhance HCV clinical care."

Merimepodib Results and Clinical Plans
In 2003, Vertex completed the treatment arms of a placebo-controlled triple combination Phase II study of merimepodib (MMPD) in combination with peg-IFN and ribavirin. This trial was designed to evaluate the safety of the triple combination in 31 patients with genotype 1 infection who did not respond to a previous course of interferon alpha in combination with ribavirin. The study provided for six months of treatment, with an optional six-month extension phase for patients who responded to therapy. Data presented by clinical investigators in 2003 demonstrated that the triple combination of MMPD + peg-IFN + ribavirin was well-tolerated and did not appear to exacerbate the incidence of hematological toxicities associated with peg-IFN and ribavirin treatment. Study results also indicated that the addition of merimepodib enhanced the antiviral activity of the peg-IFN + ribavirin combination at 24 weeks.

In a poster presented at EASL today, clinical investigators presented data on 11 patients (three subjects receiving placebo + peg-IFN + ribavirin and eight subjects receiving MMPD + peg-IFN + ribavirin) who were eligible to continue into the extension phase of the study. Ten patients completed 48 weeks of treatment. At the end of 48 weeks of treatment, the safety profile of MMPD was similar to the core 24-week study, and the majority of adverse events reported were consistent with the known side effect profile of peg-IFN and ribavirin. One of three patients in the placebo group and three of seven patients receiving MMPD who completed the extension phase achieved a sustained viral response at week 72 (24 weeks post-treatment). Based on the Phase IIa results, Vertex is planning to initiate larger studies to evaluate the ability of merimepodib to increase sustained viral response rates (SVR) in HCV-infected patients. These larger studies may involve, as before, an initial treatment period with MMPD in combination with peg-IFN and ribavirin, but followed by continued treatment with peg-IFN and ribavirin alone, a clinical approach suggested by the clinical and preclinical data to optimize the SVR.

"Merimepodib demonstrated a good tolerability profile and showed important signs of antiviral activity in this study," stated Dr. Patrick Marcellin, Professor of Medicine at University of Paris VII, and the lead investigator for the study. "Genotype 1 HCV is associated with the lowest response to therapy, and patients who are non-responsive to prior combination therapy have very limited treatment options available. These results support larger well-controlled studies in treatment-refractory patients to evaluate the ability of merimepodib to effect an increase in sustained viral response in combination with peg-IFN and ribavirin."

Vertex anticipates initiating in 2004 a Phase IIb clinical study of merimepodib in patients who are non-responsive to prior treatment with peg-IFN + ribavirin. The primary goal of this placebo-controlled study will be to evaluate the antiviral activity of a

triple combination regimen and to perform an assessment of sustained virologic response (SVR) rates. SVR is defined as an HCV-undetectable value at the end of a 24-week post-treatment follow-up period (week 72).

VX-950 Results and Clinical Plans
In oral presentations at EASL on Thursday and Friday, Vertex researchers presented a variety of preclinical results highlighting the emerging profile of VX-950. Vertex researchers demonstrated that treatment of HCV replicon cells with VX-950 decreased viral replication by 10,000 fold to undetectable levels; when the drug was subsequently removed, no rebound of viral replication was observed, suggesting that the HCV replicon had been eradicated from the treated cells. A second line of experiments showed that combination of interferon alpha with VX-950 in the HCV replicon system allowed scientists to reduce the level of VX-950 and still obtain the same degree of antiviral potency obtained with a 5-fold higher concentration of VX-950 alone.

Data presented last year at the AASLD and International HCV meetings showed that the dominant mutation(s) selected in the laboratory against VX-950 remained sensitive to BILN 2061, a protease inhibitor developed by another company which has shown antiviral activity in HCV patients, and BILN 2061 resistant mutants remained sensitive to VX-950. In the studies presented at EASL, researchers analyzed minor mutations that were cross-resistant to VX-950 and BILN 2061 in the laboratory and found that enzymatic activity of the cross-resistant HCV protease was reduced approximately 4 to 7-fold, a condition which could impair the ability of the virus to grow.

"Vertex's leadership position in the discovery of novel approaches to HCV treatment has been enhanced by the development of new technologies and approaches for evaluating the clinical potential of experimental compounds," commented Dr. Alam. "The results we have seen with VX-950 confirm our selection of HCV protease as an excellent target for the development of powerful antiviral therapies and that VX-950 has the potential of becoming a highly valuable therapeutic agent for the treatment of HCV patients."

Vertex anticipates that it will initiate a Phase I clinical trial of VX-950 in healthy volunteers in 2004. Positive results from this first Phase I study will pave the way for the first evaluation of VX-950's antiviral activity in HCV-infected patients.

Clinical Need and Market Opportunity in HCV Infection
HCV infection is a serious disease that causes inflammation of the liver, which may lead to fibrosis and cirrhosis, liver cancer, and ultimately, liver failure. Chronic hepatitis C infection afflicts approximately 2.7 million people in the U.S., many of whom are unaware of their infected status. Current treatments provide a sustained viral response for only 40 to 50 percent of patients chronically infected with genotype 1 HCV, the most difficult viral strain to treat and the most common form in the U.S. Patients who are non-responsive to current HCV therapy have limited treatment options, and clinical experience suggests that only a very low proportion of such patients achieve a sustained viral response with subsequent treatment regimens. HCV may go undetected for up to 20 years following initial infection. Worldwide, the disease strikes as many as 185 million people. Each year, 8,000 to 10,000 people in the U.S. die from complications of HCV.

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 partners. Vertex's product pipeline is principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the new HIV protease inhibitor, Lexiva(TM), with GlaxoSmithKline.

This press release may contain forward-looking statements, including statements that (i) Vertex anticipates commercializing new therapies, including merimepodib and VX-950, for the treatment of hepatitis C and that merimepodib and VX-950 each have the potential to address significant unmet needs in HCV treatment; (ii) merimepodib and VX-950 each hold promise as part of combination therapy for HCV patients who have limited treatment options and represents an attractive commercial opportunity for Vertex; (iii) further clinical study of merimepodib will be initiated in 2004; and (iv) clinical study of VX-950 will be initiated in 2004. 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 Vertex's actual results to vary materially. These risks and uncertainties include, among other things, the risks that clinical trials for merimepodib or VX-950 may not be initiated or, if initiated, may not proceed as planned due to technical, scientific, or patient enrollment issues, that results from planned clinical trials with merimepodib will not reflect the positive results from earlier trials, that positive nonclinical study results for either merimepodib or VX-950 will not be duplicated in future nonclinical or clinical studies and other risks listed under Risk Factors in Vertex's form 10-K filed with the Securities and Exchange Commission on March 15, 2004.

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Vertex Pharmaceuticals Incorporated (Nasdaq:VRTX) will host a conference call on Monday, April 26, 2004 at 5:00 pm (EDT) to discuss its first quarter 2004 financial results, at which time it will review and update its HCV product development programs. The conference call also will be webcast, and the webcast will be available to all interested parties through Vertex's website, www.vrtx.com. To access the webcast, go to the investor center and select "conference calls." To ensure a timely connection to the webcast, it is recommended that users register at least 15 minutes prior to the scheduled webcast.

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