



April 24, 2008

Vertex Announces Positive Interim Results with Telaprevir-based Therapy in Genotype 1 Chronic Hepatitis C Patients who Failed to Achieve SVR with Previous Pegylated Interferon & Ribavirin Treatment

-Interim results to be presented in late-breaker poster presentation at EASL on April 24-

-Significant early on-treatment viral response from patients who previously failed therapy-

MILAN, Italy, Apr 24, 2008 (BUSINESS WIRE) -- In a late-breaker poster presentation at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL), researchers today will present data from an interim analysis of telaprevir (VX-950) in combination with pegylated interferon and ribavirin in genotype 1 chronic hepatitis C patients who failed to achieve SVR with a previous pegylated interferon and ribavirin treatment regimen. The interim results are from the 107 study, an ongoing, open-label study which was designed to provide access to telaprevir in patients who met on-treatment criteria for null or partial response, or relapsed after the completion of 48 weeks of pegylated-interferon (peg-IFN) and ribavirin (RBV), in the control arms of the telaprevir Phase 2b PROVE studies. Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) is developing telaprevir in collaboration with Tibotec.

In the interim analysis, patients treated with telaprevir in combination with peg-IFN and RBV demonstrated a high rate of viral response at week 4 (49 of 60 patients achieved HCV RNA <25 IU/mL). This response appears to have been maintained, with no viral breakthrough observed to date in the 36 patients who have completed 4 weeks of treatment and continued out to 8 weeks and in the 16 of those patients who have continued out to 12 weeks of treatment.

"While early, these results are very promising. Patients who have not achieved SVR with prior treatment represent the largest unmet medical need in hepatitis C, as typically only 10% to 15% of those re-treated with current therapies achieve sustained virologic responses. The fact that the most difficult-to-treat patients showed such a profound early response is very encouraging," said Fred Poordad, M.D., study author of the PROVE 1 and 107 studies, and Chief of Hepatology at the Cedars-Sinai Center for Liver Disease and Transplantation.

The results will be presented in a late-breaker poster titled, "A Study of Telaprevir (TVR) with Peginterferon alfa-2A (P) and Ribavirin (R) in Subjects with Well-documented Prior P/R Null Response, Non-Response or Relapse: Preliminary Results" starting today.

Interim Data Analysis Summary - 107 Study

The 107 study results presented at EASL represent an interim analysis for patients who received telaprevir-based therapy. Patients could enroll in the 107 study if they did not achieve SVR in the control arms of the Phase 2b telaprevir studies - PROVE 1, 2 and 3. These patients were followed closely in the PROVE studies and can be well-characterized as null responders, partial responders or relapsers to standard treatment. Null responders are defined as patients who had less than a 1 log(10) decrease in HCV RNA at week four or less than a 2 log(10) decrease in HCV RNA at week 12. Partial responders are defined as patients who had a greater than 2 log(10) decrease in HCV RNA at week 12, but had detectable HCV RNA at week 24. Relapsers are defined as patients who had undetectable HCV RNA at the end of treatment but reverted to detectable levels of HCV RNA after stopping treatment.

The results include data from all enrolled patients in study 107 who received at least one dose of telaprevir-based treatment and who completed the week 4 assessment. At the time of analysis, 72 patients had received at least one dose of study drug and 60 patients had completed week 4. Patients continued treatment at week 4 and 12 if they did not meet the stopping rule criteria, defined as HCV RNA >25 IU/mL (Roche Taqman assay, version 2.0) at either of those time points. Nine patients discontinued all study treatment prior to week 12, including 5 patients who met the week 4 stopping rule, 2 patients who experienced breakthrough (both at week 2), 1 patient who discontinued due to an adverse event, and 1 patient who discontinued due to an adverse event and also met the week 4 stopping rule.

A high proportion of patients, regardless of the patient's degree of non-response to prior treatment, achieved HCV RNA <25 IU/mL at week four of treatment, and available data as of the interim analysis indicate that in patients who continued past week four, response has been maintained through week 12. Week 4, 8 and 12 on-treatment antiviral responses are summarized in the table below:

Prior Virologic Response in Phase 2 control arm studies(1)	Interim HCV RNA Results in Patients Reaching Week 4, 8 and 12 Assessments			
	Week 4 <25 IU/mL	Week 4 <10 IU/mL	Week 8 <10 IU/mL	Week 12 <10 IU/mL
Week 4 null-responder(2)	18 of 24	8 of 24	10 of 15	8 of 9
Week 12 null-responder(2)	7 of 10	5 of 10	5 of 5	3 of 3
Partial responder(3)	18 of 19	15 of 19	9 of 9	1 of 1
Breakthrough(4)	1 of 1	1 of 1	-	1 of 1
Relapsers(5)	5 of 6(a)	4 of 5(b)	6 of 6	2 of 2

(1) Each category represents a separate patient group

(2) Null responders defined as non-response week 4 (<1 log(10) drop in HCV RNA at week 4) or as non-response week 12 (<2 log(10) drop in HCV RNA by week 12)

(3) Partial responder defined as 2 log(10) drop at week 24; detectable HCV RNA at week 24

(4) Breakthrough defined as detectable HCV RNA during treatment after achieving undetectable HCV RNA

(5) Relapsers defined as undetectable HCV RNA at end of treatment, but relapsed

(a) One sample not obtained (b) Does not include missing sample

A low rate of on-treatment viral breakthrough was observed. Two patients at week 2 experienced viral breakthrough, defined as an increase in HCV RNA on treatment of >1 log(10) above HCV RNA nadir or an increase to >100 IU/mL in previously undetectable patients. Viral breakthrough has not been observed in any other patients as of this interim data analysis.

"These data provide the first demonstration of the potential for an HCV protease inhibitor-based regimen to provide significant antiviral activity in patients who have not achieved SVR with current treatments," said John Alam, M.D., Executive Vice President, Medicines Development, and Chief Medical Officer of Vertex. "While further follow-up data are needed to fully understand telaprevir's role in the re-treatment of HCV patients, we are very pleased with these early results. This is an important step forward in exploring the opportunity for telaprevir in this important patient population."

Safety Findings

In the interim analysis, adverse events were similar to those commonly observed with peg-IFN and RBV including fatigue, nausea, rash, headache, gastrointestinal disorders and anemia, and consistent with those previously reported in patients being treated with telaprevir-based therapy in the PROVE studies. Two patients discontinued treatment due to adverse events, including one discontinuation due to pleuritis/costochondritis and one due to generalized rash.

About the Phase 2a 107 Clinical Study

The 107 study is an ongoing, open-label study which was designed to provide access to telaprevir in patients who met on-treatment criteria for null or partial response, or relapsed after the completion of 48 weeks of peg-IFN and RBV in the control arms of the three telaprevir Phase 2b studies. This study provides an opportunity to correlate within individual patients the antiviral response of telaprevir, peg-IFN and RBV to that of their original responses to peg-IFN and RBV.

At the time of enrollment into the 107 study, patients were assigned to receive 12 weeks of telaprevir (750 mg q8 hour) in combination with peg-IFN and RBV at standard doses, followed by 12 weeks of peg-IFN and RBV alone. Patients who

discontinued because of adverse events in the PROVE studies were not eligible to enroll in the 107 study.

Based on the results of the PROVE 1 and PROVE 2 clinical studies, which demonstrated a correlation between RVR and SVR in a 24-week telaprevir-based regimen, and the on-treatment antiviral response observed to date in study 107, the study 107 dosing regimen is currently being modified. Partial responders and relapsers, who in the current analysis appear to have a response similar to that of treatment-naive patients, will receive the response-driven dosing regimen that is being utilized in the Phase 3 ADVANCE study. These patients will be treated for a period of 24 or 48 weeks utilizing a week 4 and week 12 undetectable HCV RNA criteria to determine which patients can stop all treatment at week 24. Partial responders and relapsers who do not achieve undetectable HCV RNA at both weeks 4 and 12 will receive 48 weeks of peg-IFN and RBV at standard doses. In order to maximize potential SVR rates in the substantial number of prior null responders who, to date, have achieved a viral response in study 107, prior null responders will be treated with 12 weeks of telaprevir-based treatment (telaprevir in combination with peg-IFN and RBV) followed by 36 weeks of peg-IFN and RBV alone.

About Telaprevir (VX-950)

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is the most advanced investigational agent in development that specifically targets HCV. Telaprevir is the first hepatitis C protease inhibitor in Phase 3 clinical trials. The Phase 3 ADVANCE trial is expected to enroll 1,050 treatment-naive genotype 1 HCV patients and will evaluate two 24-week telaprevir-based regimens in comparison to a 48-week control arm. Vertex is also conducting a global Phase 2b clinical development program of telaprevir, including PROVE 1 and PROVE 2 in treatment-naive genotype 1 HCV patients, and PROVE 3 in genotype 1 HCV patients who have not achieved SVR with a prior course of pegylated interferon-based therapy.

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 Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus, which is found in the blood of people with the disease. HCV, a serious public health concern affecting 3.4 million individuals in the United States, is spread through direct contact with the blood of infected people. Though many people with HCV infection may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Chronic HCV significantly increases a person's risk for developing long-term infection, chronic liver disease, cirrhosis or death. The burden of liver disease associated with HCV infection is increasing, and current therapies typically provide sustained benefit in less than half of patients with genotype 1 HCV, the most common strain of the virus.

Webcast from EASL at 11:00 a.m. CEST (5:00 a.m. EDT)

Vertex intends to provide a live webcast of its investor presentation from Milan beginning at 11:00 a.m. CEST (5:00 a.m. EDT) on Thursday, April 24, 2008. The presentation may be accessed from the "Events and Presentations" link on the homepage of Vertex's website at www.vrtx.com. A replay of the webcast will also be available on the Company's website until May 8, 2008. To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast.

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 cystic fibrosis. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexiva (R) is a registered trademark of the GlaxoSmithKline group of companies.

TaqMan(R) is a registered trademark of Hoffman-La Roche Inc.

Safe Harbor Statement

This press release contains forward-looking statements, including the statements that (i) telaprevir data will be featured in a late-breaker poster presentation at EASL starting on April 24, (ii) the early results from the 107 study are very promising and the fact that these patients show such a profound early response is very encouraging, (iii) these data provide the first demonstration of the potential for an HCV protease inhibitor-based regimen to provide significant antiviral activity in patients who have not achieved SVR with current treatments, and (iv) this is an important step forward in exploring the opportunity for

telaprevir in this important patient population. While the Company believes 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 promising early data provided in this press release will not be confirmed by later data from the 107 study or other ongoing or future clinical trials, the outcomes for our planned telaprevir clinical trials and studies may not be favorable, that there may be varying interpretations of data produced by one or more of our clinical trials, and other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at www.vrtx.com. We disclaim any obligation to update the information contained in this press release as new information becomes available.

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