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Researchers Report Results for 28-day Phase II Study of VX-950 in Combination with Pegylated Interferon and Ribavirin in Hepatitis C Patients

- 12 of 12 (100%) patients HCV RNA undetectable with no evidence of viral breakthrough at end of 28 days VX-950 dosing -
- 92% (11 of 12) continued to have undetectable HCV RNA through 12 weeks of follow-on therapy -

Los Angeles, CA, May 21, 2006-- Data to be presented this week at the Digestive Disease Week conference show that plasma HCV RNA was reduced to undetectable levels (less than 10 IU/mL) in all 12 of 12 (100%) patients with genotype 1 HCV infection treated with VX-950, an investigational oral hepatitis C virus (HCV) protease inhibitor being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX), in combination with pegylated interferon alfa-2a (Pegasys®; peg-IFN) and ribavirin (RBV) for 28 days. No viral breakthrough was observed in any patient during 28 days of VX-950 dosing. All patients completed dosing with no serious adverse events; those adverse events reported are considered typical of peg-IFN and RBV combination therapy. All patients enrolled in the 28-day study subsequently received follow-on treatment with peg-IFN and ribavirin. Researchers reported for the first time today that 11 of these patients (92%) continue to have no detectable virus in their blood at the end of 12 additional weeks of follow-on peg-IFN+RBV dosing. The 12th patient was found to have detectable HCV RNA (less than 30 IU/mL) in the week 12 post-VX-950 follow-up sample, with continuing evidence of detectable HCV RNA in subsequent samples. All 12 patients are continuing to receive peg-IFN+RBV.

"With the combination of VX-950, pegylated interferon and ribavirin, we observed unprecedented antiviral activity, with all 12 genotype 1 patients reaching viral levels below the limits of detection at the end of dosing at 28 days," said Eric Lawitz, M.D., of Alamo Medical Research in San Antonio, the investigator presenting the study results. "In addition, no serious adverse events were reported, and those adverse events that were reported are similar to those observed in previous studies of pegylated interferon and ribavirin. These results are highly encouraging for the initiation of future VX-950 studies that seek to evaluate the potential for viral eradication with short duration therapy."

In addition, researchers reported the results of a viral sequencing analysis from patients in the 28-day study. These results showed that despite the detection of treatment-emergent viral variants in two patients early in the course of VX-950 dosing, combination treatment with VX-950 resulted in a continuous decline in HCV RNA to undetectable levels through the initial 28-day dosing period, and HCV RNA has remained undetectable in these patients through 12 weeks of follow-on therapy.

Study Design
The 28-day, Phase II clinical study enrolled 12 treatment-naive patients with genotype 1 HCV. Patients received VX-950 in a tablet formulation at a dose of 750 mg every eight hours (q8h) for 28 days in combination with standard doses of pegylated interferon alfa-2a (Pegasy®; peg-IFN) and ribavirin (Copegus®; RBV). At the end of 28 days, patients completed dosing with VX-950 and per study protocol were required to continue off-study treatment with peg-IFN and RBV. This 28-day, Phase II study was not designed to evaluate sustained viral responses (SVR) in patients receiving VX-950.

Antiviral Results at 28 days
At study entry, the median baseline plasma HCV RNA was 6.5 log10 (3.2 million) IU/mL. At the end of week 1 (day 8 of VX-950 dosing), plasma HCV RNA was below the limit of quantitation (30 IU/mL; Roche Taqman' assay) in six of the 12 patients; and undetectable (less than 10 IU/mL; Roche Taqman' assay) in two of 12 patients. Preliminary HCV RNA results in patients for weeks 2-4 are as follows:

- At the end of week 2, plasma HCV RNA was below the limit of quantitation
- (30 IU/mL) in 11 of the 12 patients; and undetectable (less than 10 IU/mL) in three of 12 patients.
- At the end of week 3, plasma HCV RNA was below the limit of quantitation
- (30 IU/mL) in 12 of the 12 patients; and undetectable (less than 10 IU/mL) in nine of 12 patients.
- At the end of VX-950 dosing (end of week 4; day 28), plasma HCV RNA was undetectable (less than 10 IU/mL) in all 12 patients.
- No patients showed evidence of viral breakthrough while receiving VX-950 treatment.

Follow-on Therapy
All 12 patients received follow-on treatment with peg-IFN+RBV therapy after completing 28 days of combination therapy with

VX-950, peg-IFN and RBV. At week 12 of follow-on therapy, 11 patients had HCV RNA below the limit of detection (10 IU/mL). The patient with detectable viral levels at week 12 of follow-on dosing did not have undetectable HCV RNA (less than 10 IU/mL) until the 4th week of VX-950 dosing. While this patient's HCV RNA was again detectable (less than 30 IU/mL) two weeks after stopping VX-950 dosing, it was undetectable for the next 8 weeks, becoming detectable again after 12 weeks of follow-on peg-IFN+RBV dosing. At week 16 of follow-up, HCV RNA in this patient was 490 IU/mL. Blood samples from this patient are being collected for viral sequencing and this patient continues to receive peg-IFN+RBV treatment.

Safety
A complete safety review has been conducted. All patients completed dosing and no serious adverse events were reported. The most common adverse events observed in the study were flu-like illness, fatigue, headache, nausea, anemia, depression, itching and rash. All of these adverse events were mild to moderate in severity, except for one headache that was graded as severe. All of these adverse events were considered to be typical of peg-IFN and RBV combination therapy.

On-Treatment Viral Sequencing Analysis
Extensive viral sequencing analyses of the HCV protease catalytic domain were planned as part of the study, using blood samples collected at baseline (before VX-950 dosing) and during the 28-day dosing period. Baseline sequences obtained in all 12 subjects showed only wild-type RNA. Once dosing was initiated, sequences could be obtained in all 12 patients at the 24-hour time point, but only in two patients at the end of the first week of dosing (14 on-treatment samples total). In all other patients, and at all other time points, dosing with VX-950 in combination with peg-IFN and RBV suppressed plasma HCV RNA to levels below the limit of detection of the sequencing assays.

Using a highly sensitive clonal sequencing approach, 12 of the 14 samples contained 100% wild-type virus. In two samples, one collected from a patient at 24 hours of dosing and one in another patient at the end of the first week of dosing, viral variants consisting predominantly of a V36M amino acid sequence change were detected, with one sample also showing a low proportion of an A156T amino acid sequence change. In both these patients with detectable viral variants, HCV RNA was rapidly suppressed during continued dosing with VX-950, and both patients became HCV RNA undetectable by the end of the third week of dosing. HCV RNA remained undetectable in both of these patients after 12 weeks of follow-on treatment with peg-IFN and RBV. The results suggest that viral variants may exist at a low level in patients before VX-950 dosing is initiated, and that they are uncovered by the rapid reduction of the wild-type virus. However, in this study these variants were rapidly suppressed to below detectable levels with VX-950, peg-IFN and RBV combination therapy.

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 hepatitis C may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Hepatitis C 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 only provide sustained benefit in about 50% of patients with genotype 1 HCV, the most common strain of the virus. Specifically targeted antiviral therapies for HCV in clinical development have the potential to increase the proportion of patients who can eradicate the virus.

About VX-950
VX-950 is an investigational oral inhibitor of hepatitis C virus protease, an enzyme essential for viral replication, and is one of the most advanced investigational agents that specifically targets HCV. In clinical studies to date of 14 days and 28 days duration, researchers have observed rapid and dramatic antiviral activity with VX-950 dosed both as a single agent and in combination. In clinical studies of VX-950 no patients have discontinued treatment and no serious adverse events have been reported. The most common adverse events reported, including patients who did not receive VX-950, and regardless of possible relationship to drug, have been headache, frequent urination, gastrointestinal symptoms, myalgias, skin disorders and chills. Most of these adverse events have been reported as mild to moderate in severity.

Vertex researchers were the first to solve the three-dimensional crystal structure of HCV protease, and have used structural insights to enable the design of small molecule HCV protease inhibitors, including VX-950.

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 principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

About Digestive Disease Week (DDW)
DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association, the American Society for Gastrointestinal Endoscopy and the Society

for Surgery of the Alimentary Tract, DDW takes place May 20-25, 2006, at the Los Angeles Convention Center. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org.

Safe Harbor Statement
This press release may contain forward-looking statements, including a statement that results from the Phase II study are encouraging for the design of future VX-950 studies that seek to evaluate the potential for short-course, therapy that eliminates the virus from most patients. 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 (i) full analysis of the data, or further testing, will not reflect the results reported in this press release, or support any or all of the conclusions provided in this press release; and (ii) clinical trials for VX-950 may not proceed as planned due to technical, scientific, or patient enrollment issues, clinical trial results may not be available when expected, or expected regulatory filings may not occur or may be delayed due to adverse clinical or non-clinical trial developments or unanticipated FDA action; and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies, and Pegasys is a registered trademark of Hoffman-La Roche Inc.

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