



HCV ADVOCATE EASL 2007 NEWS REVIEW

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Interim Results Presented at EASL from PROVE 1 Clinical Trial of Investigational Drug Telaprevir in Patients with Genotype 1 Hepatitis C

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PROVE 1 data support potential to shorten treatment duration in treatment-naïve, genotype 1 HCV patients

Barcelona, Spain, April 14, 2007 – In a late-breaker

presentation at the 42nd Annual Meeting of the European Association for the Study of the Liver (EASL), researchers today presented data from a planned interim analysis of the PROVE 1 clinical trial, which is the first trial to evaluate short-duration therapy with the investigational hepatitis C protease inhibitor telaprevir (TVR, VX-950) in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) in treatment-naïve, genotype 1-infected hepatitis C patients. The data from PROVE 1 demonstrated a high rate of rapid viral response (RVR) in the telaprevir groups and a low rate of on-treatment viral breakthrough, and suggested that 12 weeks of telaprevir-based therapy enabled some patients to clear the virus. Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) is developing telaprevir in collaboration with Tibotec.

“The high rates of RVR observed in the telaprevir groups in PROVE 1, and the fact that some patients have remained persistently viral negative 20 weeks after stopping the 12 weeks of telaprevir-based therapy, suggest that we may be able to shorten the treatment duration in genotype 1 HCV patients,” said John McHutchison, M.D., Principal Investigator for the PROVE 1 study and Director of Gastroenterology and Hepatology Research at Duke Clinical Research Institute. “These interim results are encouraging and suggest that high sustained viral response (SVR) rates may be achieved with regimens that are 24 weeks in total duration. We look forward to 24 week follow-up data from the initial group of patients who stopped treatment at 12 weeks, and follow-up data from patients in the study who received 24 weeks of treatment.”

PROVE 1 Summary

- 88% and 79% of patients receiving telaprevir achieved a rapid viral response (RVR) as measured by plasma HCV RNA <30 IU/mL and <10 IU/mL, respectively, at 4 weeks.
- Six of 9 patients in one treatment arm who completed 12 weeks of treatment, and who had achieved an RVR as defined by the study protocol (<10 IU/mL), continued to

have undetectable HCV RNA 20 weeks after stopping all treatment (“SVR20”).

- The treatment discontinuation rate due to adverse events through 12 weeks was 11% in telaprevir arms and 3% in the control arm. Rash, gastrointestinal events and anemia were the most common events leading to discontinuation in the telaprevir arms.

“These interim results support our approach to evaluating telaprevir-based regimens of differing durations in our Phase 2 program. The results of the 12-week duration regimen provide a level of confidence in the shorter duration approach, and we look forward to safety and antiviral data, including SVR data, from the 24-week telaprevir-based regimens,” said John Alam, M.D., Executive Vice President, Medicines Development, and Chief Medical Officer of Vertex. “The information from PROVE 1 and PROVE 2 should allow us to design optimized durations and regimens for Phase 3 development.”

PROVE 1 and PROVE 2 represent two of three large, ongoing clinical studies of telaprevir. In aggregate, the three studies are designed in part to evaluate the safety and antiviral activity of different durations of telaprevir-based therapy in genotype-1 infected HCV treatment-naïve and treatment-failure patients, both with and without ribavirin. Taken together, the PROVE studies are expected to provide information to optimize the treatment duration and treatment regimen for telaprevir-based therapy.

PROVE 1: Implications for Clinical Development and Registration Path

Vertex today discussed the potential implications that the new information from PROVE 1 has for future clinical development of telaprevir. Vertex stated its intention to consider evaluation of treatment regimens that would include telaprevir in combination with peg-IFN and RBV, and depending on PROVE 2 data, regimens that may exclude RBV. Vertex expects to focus on treatment durations of no more than 24 weeks. Vertex and Tibotec are planning to meet with regulatory authorities to

discuss the Phase 3 design in mid-2007 and are planning to initiate Phase 3 clinical development in the fourth quarter of 2007. The registration strategy and timing of an NDA filing will be dependent on discussions with regulatory authorities.

PROVE 1 Results at EASL

Interim 12-week antiviral analysis of PROVE 1

A total of 250 patients were enrolled in PROVE 1 and received at least one dose of telaprevir or placebo in addition to Peg-interferon alfa-2a (peg-IFN) + ribavirin (RBV) in the study. A total of 175 patients received at least one dose of telaprevir in 1 of 3 arms (treatment arms B, C and D) and 75 patients received at least one dose of placebo (arm A). Treatment with telaprevir resulted in a high proportion of patients achieving a rapid viral response at 4 weeks. At the time of the interim analysis, all patients had either completed 12 weeks or discontinued from the study prior to week 12. Available 4-week and 12-week results are detailed in the following table:

Interim HCV RNA results for Patients Enrolled in the PROVE 1 Trial				
Treatment Assignment	Patients with HCV RNA <30 IU/mL at end of 4 weeks of dosing	Patients with HCV RNA <10 IU/mL at end of 4 weeks of dosing	Patients with HCV RNA <10 IU/mL at end of 12 weeks of dosing, DC=F *	Patients with HCV RNA <10 IU/mL at end of 12 weeks of dosing (last on-treatment value carried forward)
TVR + peg-IFN + RBV (arms B, C and D)	153 of 175 (88%)	138 of 175 (79%)	123 of 175 (70%)	149 of 175 (85%)
Placebo + peg-IFN + RBV (arm A)	12 of 75 (16%)	8 of 75 (11%)	29 of 75 (39%)	32 of 75 (43%)
* Intent-to-treat, discontinuation=failure analysis. Patients who had HCV RNA <10 IU/mL at the time of discontinuation are counted as "failures", however these patients will be followed post-discontinuation to determine if they achieve a sustained viral response (SVR).				

In PROVE 1, a low rate of viral breakthrough was observed. Viral breakthrough occurred in 12 patients receiving telaprevir (7%), all but one of which occurred in the first 4 weeks of treatment.

Analysis of PROVE 1 Patients who Finished All Treatment at 12 Weeks

Seventeen of 175 patients received at least one dose of telaprevir in “Arm D” of the PROVE 1 study (telaprevir + peg-IFN + RBV). According to the study protocol, patients in Arm D were eligible to stop all treatment at week 12 if they met on-treatment criteria, including the achievement of RVR (<10 IU/mL at week 4) and maintenance of this viral response (<10 IU/mL) at week 10 of treatment. Nine of 17 patients met these criteria and stopped therapy at 12 weeks, and 6 of these patients continued to have undetectable HCV RNA at week 20 of post-treatment follow-up. Of the remaining 8 patients enrolled in Arm D, 4 discontinued due to adverse events prior to week 12, and 4 did not achieve RVR.

Interim 12-Week Safety Analysis of PROVE 1

In PROVE 1, the types of adverse events that have been commonly observed with interferon and ribavirin were seen across all treatment arms. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. Gastrointestinal disorders, rash and anemia were more common in the telaprevir arms.

In the telaprevir dosing arms, the incidence of treatment discontinuations due to adverse events through 12 weeks was 11% (19 of 175 patients), compared to 3% (2 of 75 patients) in the control arm. The difference between the two groups is due to the greater number of discontinuations due to rash, gastrointestinal disorders and anemia in the telaprevir arms compared to the control arm. The most common reason for treatment discontinuation in the telaprevir arms was rash (7 patients), and the median time to discontinuation in these patients was 64 days.

Webcast of Investor Presentation

Vertex intends to provide a live webcast of its investor presentation from Barcelona beginning at 7:30 p.m. CEST (1:30 p.m. EDT) on Saturday, April 14. The presentation may be accessed from the ‘Events Calendar’ 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 April 27, 2007. To ensure a timely connection, it is recommended that users register

at least 15 minutes prior to the scheduled webcast.

About Telaprevir (VX-950)

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is one of the most advanced investigational agents in development that specifically targets HCV. Vertex is conducting a global Phase 2b clinical development program for telaprevir consisting of three large clinical trials that are expected to enroll approximately 1,000 patients with genotype-1 HCV at clinical centers in the United States, Canada and Europe. In these clinical trials, telaprevir is being dosed as 750 mg every eight hours in combination with pegylated interferon alfa-2a (Pegasys®), both with and without ribavirin (Copegus®).

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 infection with hepatitis C virus (HCV), which is found in the blood of people with the disease. HCV, a serious public health concern affecting 170 million people worldwide, is spread through direct contact with the blood of an infected person. 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 of developing chronic liver disease, cirrhosis, liver cancer and early death.

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.

About Tibotec

Tibotec Pharmaceuticals, Ltd., based in Cork, Ireland, is a pharmaceutical research and development company. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS drugs and anti-infectives for diseases of high unmet medical need. The Company's main research and development facilities are in Mechelen, Belgium with offices in Yardley, PA. For further information on Tibotec, please visit www.tibotec.com

Safe Harbor Statement

This press release may contain forward-looking statements, including statements that (i) PROVE 1 data support potential to shorten treatment duration and increase SVR rates in patients with genotype 1 HCV infection; (ii) 12 weeks of telaprevir-based therapy enabled some patients to clear the virus; (iii) high SVR rates with telaprevir may be achieved with regimens that are no longer than 24 weeks in duration; (iv) interim results support our approach to evaluating telaprevir-based regimens of differing durations in our Phase 2 program; (v) the information from PROVE 1 and PROVE 2 will allow us to design optimized durations and regimens for Phase 3 development; (vi) the PROVE studies are expected to provide information to optimize treatment duration and treatment regimen for telaprevir-based therapy; (vii) Vertex will consider evaluation of treatment regimens that would include telaprevir in combination with peg-IFN and RBV, and depending on PROVE 2 data, regimens that may exclude RBV; (viii) Vertex expects to focus on treatment durations of no more than 24 weeks; and (ix) Vertex and Tibotec are planning to meet with regulatory authorities to discuss the Phase 3 design in mid-2007 and are planning to initiate Phase 3 clinical development in the fourth quarter of 2007. 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 observed outcomes in clinical investigations of small numbers of patients will not be reflected in clinical trials involving larger numbers of patients, that unexpected and adverse outcomes in other ongoing clinical and nonclinical studies will occur, that the FDA or other regulatory authorities will require additional and unanticipated studies or clinical trial outcomes before granting regulatory approval, 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.

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Human Genome Sciences Reports Positive Interim Results of Phase 2b Trial of Albuferon(R)

<http://www.pr-inside.com>

ROCKVILLE, Md., April 14 /PRNewswire-FirstCall/ -- Human Genome Sciences, Inc. today reported results at Week 12 following the completion of therapy (SVR12) in a Phase 2b clinical trial of Albuferon(R) (albinterferon alfa-2b) in combination with ribavirin in patients with genotype 1 chronic hepatitis C who are naive to interferon alpha-based treatment regimens. The results were presented over the weekend in Barcelona at the 42nd Annual Meeting of the European Association for the Study of the Liver (EASL).

"The interim data presented at EASL suggest that Albuferon may offer efficacy at least comparable to peginterferon alfa-2a, with half the injections and the potential for less impairment of quality of life," said Stefan Zeuzem, M.D., Professor of Medicine and Chief, Department of Medicine, J.W. Goethe University Hospital (Frankfurt, Germany), and a clinical investigator in the Phase 2b trial. "We look forward to continuing the evaluation of Albuferon in larger populations in Phase 3 trials."

The interim results of the Phase 2b trial demonstrated that Albuferon provided at least comparable efficacy vs. Pegasys. The treatment group receiving Albuferon 900-mcg doses every two weeks achieved a 59% rate of sustained virologic response at 12 weeks following completion of therapy (SVR12), vs. 54% for Pegasys administered once every week (ITT analysis). This Albuferon treatment group also had more favorable health-related quality-of-life scores than the Pegasys treatment group. All Albuferon doses provided efficacy at least comparable to Pegasys. Among treatment-adherent patients, 73% of those in the combined groups receiving Albuferon every two weeks achieved SVR12, versus 63% for patients receiving Pegasys once a week.

Interim Results by Treatment Group

The interim results of the Phase 2b trial at Week 12 following the completion of therapy include the following virologic response rates (SVR12) and other findings:

Albuferon 900-mcg Every Two Weeks (Albuferon 900 Q2) -- Based on an intention-to-treat (ITT) analysis, 59% of patients in the Albuferon 900 Q2 treatment group achieved SVR12, vs. 54% for Pegasys administered every week. -- Among treatment-adherent patients, 74% of those in the Albuferon 900 Q2 treatment group achieved SVR12, versus 63% for Pegasys. -- In heavier patients (greater than or equal to 75 kg) who were treatment-adherent, 81% of those in the Albuferon 900 Q2 treatment group achieved SVR12, versus 57% for Pegasys. -- Based on the SF-36 Health Survey, patients in the Albuferon 900 Q2 treatment group

reported less impairment of health-related quality of life, compared with patients in the Pegasys treatment group, as measured by both physical component and mental component SF-36 summary measures at all time-points throughout the 48-week treatment period. -- At Weeks 12 and 24, fewer working patients in the Albuferon 900 Q2 treatment group reported missing 7 days or more of work during the previous month, vs. the Pegasys group (Week 12: 4% for Albuferon 900 Q2 vs. 17% for Pegasys; Week 24: 5% for Albuferon 900 Q2, vs. 22% for Pegasys). -- The rate of discontinuations due to adverse events was 9% in the Albuferon 900 Q2 treatment group, vs. 6% in the Pegasys group.

"The 900-mcg Albuferon dose has the potential to offer patients an attractive therapeutic option, given the favorable antiviral response data, more favorable quality of life effects, and half as many injections," said David C. Stump, M.D., Executive Vice President, Research and Development, HGS.

Albuferon 1200-mcg Every Two Weeks (Albuferon 1200 Q2)
-- ITT analysis shows that 56% of patients in the Albuferon 1200 Q2 treatment group achieved SVR12, vs. 54% for Pegasys administered every week. -- Among treatment-adherent patients, 72% of those in the Albuferon 1200 Q2 treatment group achieved SVR12, versus 63% for Pegasys. -
- In heavier patients (greater than or equal to 75 kg) who were treatment-adherent, 70% of those in the Albuferon 1200 Q2 treatment group achieved SVR12, versus 57% for Pegasys every week. -- ITT analysis shows that the Albuferon 1200 Q2 treatment group exhibited a robust early antiviral response (reduction in hepatitis C RNA viral load to below the level of quantitation): 75% for Albuferon 1200 Q2 at Week 12, vs. 66% for Pegasys. The Albuferon 1200 Q2 treatment group also had the most rapid time to HCV RNA negativity. -- The rate of discontinuations due to adverse events was 19% in the Albuferon 1200 Q2 treatment group, vs. 6% in the Pegasys group. Adverse events observed were

those typically expected with interferon therapy. Dose reductions were attempted in only 29% of subjects prior to discontinuation, versus 43% for Pegasys.

"In the Albuferon Phase 3 trials, we will strongly encourage titration of dose where necessary to ensure tolerability and maximize the therapeutic benefit of the robust early antiviral response offered by the 1200-microgram dose on a two-week administration schedule," said Dr. Stump.

Albuferon 1200-mcg Every Four Weeks (Albuferon 1200 Q4) -- ITT analysis shows that 53% of patients in the Albuferon 1200 Q4 treatment group achieved SVR12, vs. 54% for Pegasys administered every week. -- Among treatment-adherent patients, 68% of those in the Albuferon 1200 Q4 treatment group achieved SVR12, versus 63% for Pegasys. - - In heavier patients (greater than or equal to 75 kg) who were treatment-adherent, 67% of those in the Albuferon 1200 Q4 treatment group achieved SVR12, versus 57% for Pegasys administered once every week. -- The rate of discontinuations due to adverse events was 12% in the Albuferon 1200 Q4 treatment group, vs. 6% in the Pegasys group. Dose reductions due to hematologic adverse events were lowest in the group receiving 1200-mcg Albuferon every four weeks (6% vs. 23% for Pegasys).

"We are encouraged that Albuferon 1200-mcg dosed monthly achieved comparable efficacy vs. Pegasys despite lower early virologic response," said

Dr. Stump. "We and our collaborator, Novartis, are currently planning an additional study to identify the optimal dose for Albuferon dosed monthly."

The interim Phase 2b results presented at EASL on Saturday, April 14 (Zeuzem S, Benhamou Y, Bain V, McHutchison J, et al), include data available through Week 12 following completion of 48 weeks of therapy for 458 patients who were enrolled in the randomized, open-label, multi-center, active- controlled, dose-ranging trial. The study was conducted in Australia, Canada,

Czech Republic, France, Germany, Israel, Poland and Romania. Patients were randomized into four treatment groups, three of which received subcutaneously administered Albuferon (900 mcg every two weeks, 1200 mcg every two weeks, and 1200 mcg every four weeks). The fourth treatment group serves as the active control group and received 180-mcg doses of subcutaneously administered peginterferon alfa-2a (Pegasys) once a week. All patients received weight-based oral ribavirin daily. The primary efficacy endpoint is sustained virologic response (SVR), defined as undetectable viral load (HCV RNA < 10 IU/mL) at 24 weeks following completion of therapy. Interim results at Week 12 following completion of therapy are regarded as highly predictive of SVR.

Interim Results of Phase 2 Trial in Genotype 2 or 3 Chronic Hepatitis C

An additional presentation at EASL reported the interim results at Week 12 following the completion of therapy (SVR12) in a randomized Phase 2 trial of Albuferon in combination with ribavirin in 43 treatment-naive patients with genotype 2 or 3 chronic hepatitis C (CHC). The interim results demonstrated that Albuferon dosed at 1500 mcg every four weeks was well tolerated and exhibited robust antiviral activity in these patients. Dose reductions due to hematologic adverse events stabilized by Week 8 and recovered upon completion of therapy. These results support additional evaluation of Albuferon in combination with ribavirin in a Phase 3 trial in patients with genotypes 2 and 3 CHC. The results also support further evaluation of Albuferon at higher doses with monthly administration.

About Albuferon

Albuferon is a novel long-acting form of interferon alpha created by HGS using its proprietary albumin fusion technology. Albuferon results from the genetic fusion of human albumin and interferon alpha. Human albumin is the most prevalent naturally occurring blood protein in the human circulatory system, persisting in circulation in the body for over twenty days. Research has shown that genetic fusion of therapeutic proteins to human albumin

decreases clearance and prolongs the half-life of the proteins. Recombinant interferon alpha is approved for the treatment of hepatitis C, hepatitis B and a broad range of cancers.

Albuferon is being developed by HGS and Novartis under an exclusive worldwide development and commercialization agreement entered into in June 2006. Under the agreement, HGS and Novartis will co-commercialize Albuferon in the United States, and will share clinical development costs, U.S. commercialization costs and U.S. profits equally. Novartis will be responsible for commercialization in the rest of the world and will pay HGS a royalty on those sales. Clinical development, commercial milestone and other payments to HGS could total as much as \$507.5 million, including \$92.5 million received to date.

About Hepatitis C

Hepatitis C is an inflammation of the liver caused by the hepatitis C virus. It is estimated that as many as 170 million people worldwide are infected with hepatitis C virus. This includes nearly four million people in the United States. When detectable levels of the hepatitis C virus in the blood persist for at least six months, a person is diagnosed as having chronic hepatitis C. The hepatitis C virus can cause serious liver disease in a significant proportion of infected individuals, leading to cirrhosis, primary liver cancer, and even death.

About Human Genome Sciences

The mission of HGS is to apply great science and great medicine to bring innovative drugs to patients with unmet medical needs.

The HGS clinical development pipeline includes novel drugs to treat hepatitis C, lupus, anthrax disease, cancer, rheumatoid arthritis and HIV/AIDS. The Company's primary focus is rapid progress toward the commercialization of its two lead compounds, Albuferon(R) for hepatitis C, and LymphoStat-B(R) for lupus. Phase 3 clinical trials of both compounds are now underway.

In June 2006, HGS announced that the U.S. Government exercised its option under an existing contract to purchase 20,000 doses of ABthrax(TM) for the treatment of anthrax disease. Other HGS drugs in clinical development include two TRAIL receptor antibodies for the treatment of hematopoietic and solid malignancies, in addition to an antibody to the CCR5 receptor for the treatment of HIV/AIDS.

For more information about HGS, please visit the Company's web site at <http://www.hgsi.com/> . For more information about Albuferon or to download copies of the EASL presentations, please visit <http://www.hgsi.com/products/albuferon.html> . To view the presentation of interim results of the Phase 2b trial of Albuferon in treatment-naïve genotype 1 hepatitis C patients, click here. To view the presentation of interim results of the Phase 2 trial of Albuferon in treatment-naïve genotype 2 or 3 hepatitis C patients, click here. Health professionals or patients interested in Albuferon clinical trials or other studies involving HGS products may inquire via the Contact Us section of the Company's web site, <http://www.hgsi.com/products/request.html> , or by calling us at (301) 610-5790, extension 3550.

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Safe Harbor Statement

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on Human Genome Sciences' current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of the Company's unproven business model, its dependence on new technologies, the uncertainty and timing of clinical trials, the Company's ability to develop and commercialize products, its dependence on collaborators for services and revenue, its substantial indebtedness and lease

obligations, its changing requirements and costs associated with planned facilities and clinical trials, intense competition, the uncertainty of patent and intellectual property protection, the Company's dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks described in the Company's filings with the Securities and Exchange Commission. In addition, the Company will continue to face risks related to animal and human testing, to the manufacture of ABthrax and to FDA concurrence that ABthrax meets the requirements of the ABthrax contract. If the Company is unable to meet the product requirements associated with the ABthrax contract, the U.S. Government will not be required to reimburse the Company for the costs incurred or to purchase any ABthrax doses. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. Human Genome Sciences undertakes no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise.

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BARACLUDGE(R) (entecavir) Therapy Resulted In Undetectable Levels Of Hepatitis B Virus In Cohort Of Patients Who Re-Started Treatment

Bristol-Myers Squibb Company (NYSE: BMY) today announced data from a cohort of nucleoside-naive HBeAg-negative chronic hepatitis B patients (ETV-027/901, n=99). These data showed that patients who experienced recurrent levels of hepatitis B virus in the blood after interruption of treatment with BARACLUDGE(R) (entecavir) achieved viral suppression and liver enzyme (ALT) normalization when re-treated for 48 weeks with BARACLUDGE.

The study results were presented at the 42nd Annual Meeting of the European Association for the Study of Liver Diseases (EASL) in Barcelona, Spain.

In this cohort, 93 percent of patients who were re-treated with BARACLUDE had undetectable viral load - the level of the hepatitis B virus in the blood - (HBV DNA <300 copies/mL, measured by a common assay - polymerase chain reaction or PCR) and 83 percent achieved liver enzyme normalization (ALT less than or equal to 1xULN) after 48 weeks of therapy.

"This study showed that when treated again with BARACLUDE for 48 weeks, patients achieved responses similar to those seen prior to treatment interruption, with safety results consistent with previously reported experience," said Hakan Senturk, MD, of the Ist.Univ.Cerrahpasa Tip Fak, Istanbul, Turkey.

No deaths or treatment discontinuations due to adverse events were reported in this cohort. The most common adverse events occurring in greater than 10 percent of patients were abdominal pain, fatigue, upper respiratory tract infection, nasopharyngitis, increased ALT, arthralgia, and headache.

About the Nucleoside-Naive HBeAg-Negative BARACLUDE(R) (entecavir) Re- Treatment Cohort

This analysis evaluated BARACLUDE(R) (entecavir) in nucleoside-naive chronic HBeAg-negative patients who discontinued study therapy in ETV-027, and subsequently restarted treatment in rollover study ETV-901, with a greater than 60 day gap between end of treatment in study ETV-027 and start of treatment in study ETV-901.

-- ETV-027 compared 0.5 mg of BARACLUDE vs. 100 mg of lamivudine in nucleoside-naive chronic HBeAg-negative chronic hepatitis B patients.

-- Rollover study ETV-901 was established as an open-label, follow-up protocol for patients in phase II and III studies of

BARACLUDE.

-- Due to ongoing blinding of study ETV-027, most patients retreated in ETV-901 initially received a combination of 1 mg of BARACLUDE plus 100 mg of lamivudine, and were subsequently switched to 1 mg of BARACLUDE monotherapy.

The analysis cohort was defined regardless of treatment response at the end of dosing in study ETV-027, and independent of virologic or ALT measurements at the start of dosing in study ETV-901. During off-treatment follow-up, the majority of patients had recurrent levels of hepatitis B virus in the blood (viremia) and increases in ALT.

Data Results

At the end of dosing for study ETV-027:

-- 94 percent (n=93/99) of the re-treatment cohort had undetectable viral load

-- 78 percent (n=77/99) had ALT normalization

At entry into ETV-901:

-- Four percent (n=4/99) of patients had undetectable viral load

-- Eight percent (n=8/97) of patients had ALT normalization

Following re-treatment in study ETV-901:

-- 93 percent (n=82/88) of patients had undetectable viral load (HBV DNA <300 copies/mL) by week 48 of re-treatment with BARACLUDE

-- 83 percent (n=79/95) of patients had ALT normalization (ALT less than or equal to 1 times the upper limit of normal) by week 48 of re-treatment BARACLUDE

Adverse events in study ETV-027/901 re-treatment cohort:

-- 67 percent (n=66/99) of patients experienced an adverse event. The most common adverse events occurring in greater than ten percent of patients were abdominal pain, fatigue, upper respiratory tract infection, nasopharyngitis, increased ALT, arthralgia, and headache.

-- There were no deaths or treatment discontinuations due to adverse events.

-- Nine percent (n=9/99) of patients experienced a serious adverse event. Serious adverse events included ALT elevation or hepatitis exacerbation (4), bilirubin elevation (1), inguinal hernia (1), sialoadenitis (1), thrombocytopenic purpura (1), groin pain (1), macular edema (1), urinary incontinence (1) and cholelithiasis (1). Two of these events, hepatitis exacerbation (1) and thrombocytopenia (1), were considered possibly related to treatment by the investigator.

-- Five percent (n=5/99) of patients experienced an ALT flare on treatment (ALT > 2 times baseline and >10 times the upper level of normal)

About BARACLUDE(R) (entecavir)

Discovered at Bristol-Myers Squibb, BARACLUDE(R) (entecavir) is a nucleoside analogue indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication with either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. BARACLUDE has been approved in more than 60 countries and regions around the world.

Important Information About BARACLUDE(R) (entecavir) 0.5mg/1mg Tablets

BARACLUDE(R) (entecavir) is a prescription medicine used for chronic infection with hepatitis B virus (HBV) in adults where the

virus is multiplying and damaging the liver. BARACLUDE does not cure HBV or stop the spread of HBV to others.

People should not take BARACLUDE if they are allergic to it or any of its ingredients. BARACLUDE has not been studied in children and is not recommended for anyone less than 16 years of age.

People taking BARACLUDE(R) (entecavir) should tell their healthcare provider right away if they feel very weak or tired, have unusual muscle pain, have trouble breathing, have stomach pain with nausea and vomiting, feel cold - especially in their arms and legs, feel dizzy or lightheaded, or have a fast or irregular heartbeat, as they may be signs of a serious condition called lactic acidosis (buildup of an acid in the blood).

Lactic acidosis is a medical emergency and must be treated in the hospital. Some people who have taken medicines like BARACLUDE have developed serious liver problems called hepatotoxicity. This may occur with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

People should call their healthcare provider right away if they get any of the following signs of liver problems: yellowing (jaundice) of the skin or the white part of the eyes, darkening of the urine, lightening in the color of bowel movements (stools), not feeling like eating food for several days or longer, feeling sick to the stomach (nausea), or having lower stomach pain. Lactic acidosis and hepatotoxicity have happened in some people taking medicines like BARACLUDE.

In some people, hepatitis B symptoms may get worse or become very serious when they stop taking BARACLUDE. People should not stop BARACLUDE without talking to their healthcare provider. Healthcare providers will need to follow their patients and do blood tests to check the liver when BARACLUDE is stopped. People should tell their healthcare provider if they have or develop kidney problems because their healthcare provider may want to do tests to see if a lower dose is needed or a different dose schedule.

Because BARACLUDE is removed from the body through the kidneys, a lower dose or a different dose schedule may be required. Healthcare providers may want to perform tests to determine whether a patient needs a lower dose or should take BARACLUDE less often than once a day.

It is not known if BARACLUDE is safe to use during pregnancy. It is not known if BARACLUDE helps to prevent a pregnant mother from passing HBV to her baby. A pregnant woman and her healthcare provider will need to decide if BARACLUDE is right for her. A woman should not breastfeed if she is taking BARACLUDE.

People should discuss with their healthcare provider all prescription and non-prescription medicines, vitamins, herbal supplements, and other health preparations they are taking or plan to take. BARACLUDE(R) (entecavir) may interact with medicines that leave the body through the kidneys. The most common side effects of BARACLUDE in clinical studies were headache, tiredness, dizziness, and nausea.

This list of side effects is not complete at this time because BARACLUDE is still under study. People should report any new or continuing symptom to their healthcare provider. BARACLUDE should be taken once daily on an empty stomach (at least two hours after a meal and two hours before the next meal). To learn more about BARACLUDE and for Full Prescribing Information, including boxed WARNINGS, please visit <http://www.bms.com>.

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.

BARACLUDE(R) (entecavir) is a trademark of Bristol-Myers Squibb Company.

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<http://www.bms.com>

ViroPharma Announces Presentation of Additional HCV-796 Data at Meeting of The European Association for the Study of the Liver

<http://www.prnewswire.com>

- Phase 1b Combination Data Highlight Favorable Tolerability and Additive Antiviral Activity of HCV-796 -

EXTON, Pa., April 13 /PRNewswire-FirstCall/ -- ViroPharma Incorporated (Nasdaq: [VPHM](#)) today announced additional data from a Phase 1b study of HCV-796, a unique, orally dosed hepatitis C virus (HCV) polymerase inhibitor at the 42nd Annual Meeting of the European Association for the Study of the Liver (EASL). This meeting is being held in Barcelona, Spain. These data on the antiviral activity and tolerability of twice daily HCV-796 in combination with pegylated interferon alfa-2b (peg-IFN) elaborate on previously presented data. HCV-796 is currently undergoing Phase 2 evaluation and is being co-developed with Wyeth Pharmaceuticals, a division of Wyeth (NYSE: [WYE](#)).

These Phase 1b combination data demonstrate the additive antiviral effects of HCV-796 across multiple genotypes of hepatitis C virus, **in treatment-naive adult subjects with chronic hepatitis C infection**. HCV-796 dosed twice daily plus peg-IFN displays clinical antiviral activity that is greater than that of HCV-796 or peg-IFN alone across all dose cohorts and tested HCV genotypes. Final safety and tolerability data show that HCV-796 is generally well tolerated when added to peg-IFN. Adverse events were generally consistent with known effects of interferons. No dose-limiting toxicities were observed across the range of HCV-796 study doses.

Phase 1b Clinical Trial Design

This 14 day randomized, double-blind, placebo-controlled, sequential-group study of ascending multiple doses enrolled subjects with chronic HCV infection who were naive to treatment. Subjects were enrolled in sequential, ascending dose cohorts with a target of 16 subjects (12 subjects receiving HCV-796 BID and 4

receiving placebo in each cohort). The first cohorts assessed the effect of HCV-796 as monotherapy compared to placebo (data from which were released on November 10, 2005). Subsequent cohorts were comprised of subjects who received peg-IFN (PEG-Intron; 1.5 ug/kg/dose) on days -1 and 7 in combination with either placebo or HCV-796 (100 mg, 250 mg, 500 mg or 1000 mg) every 12 hours, from days 1 to 14. Antiviral Activity Results

Data are available through treatment day 14 from subjects in four combination treatment groups (n= 10 to 12 subjects per group) and on 19 subjects who received peg-IFN alone.

-- For genotype 1, mean reduction from baseline ranged from 1.5 to 2.3 log₁₀ on day 7 and from 2.6 to 3.2 log₁₀ on day 14 in the combination therapy groups compared to 0.9 log₁₀ on day 7 and 1.3 log₁₀ on day 14 for peg-IFN alone.

-- For non-genotype 1, mean reduction from baseline ranged from 2.8 to 3.5 log₁₀ on day 7 and from 3.5 to 4.8 log₁₀ on day 14 in the combination therapy groups compared to 1.5 log₁₀ on day 7 and 2.6 log₁₀ on day 14 for peg-IFN alone.

-- Viral reduction greater or equal to 2.0 log₁₀ at day 14 was achieved in 70 to 92 percent of subjects in all combination groups compared to 40 percent on peg-IFN alone.

-- At day 14, 30 to 33 percent of patients in the combination groups receiving greater than or equal to 250 mg BID of HCV-796 achieved viral levels below the quantification limit of 50 IU/mL HCV RNA.

Safety and Tolerability Results

A safety review of HCV-796 in combination with peg-IFN has been completed. Combination therapy including HCV-796 was found to be generally well tolerated. The observed safety profile supports the evaluation of HCV-796 in studies of longer duration.

-- Adverse events across all dose cohorts were generally mild to moderate in severity and were characteristic of the known side effects of interferons.

-- Adverse events that occurred at a frequency of greater than 15 percent across all dose cohorts of HCV-796 plus peg-IFN and peg-IFN alone included headache, chills, myalgias, fever, pain, arthralgia and rash.

-- There were two reports of serious adverse events: one in the placebo arm (pneumonia), and one in the 1000 mg combination cohort (seizure and rhabdomyolysis in a subject receiving high dose methadone chronically).

-- The rate of discontinuation due to adverse events was low across the study. No patient discontinued due to adverse events in the 100, 250, or 500 mg dose cohorts. In the peg-IFN alone group, one patient discontinued due to hypertension; of those that received 1000 mg HCV-796 plus peg-IFN, three patients discontinued due to either vasovagal syncope after a blood draw, rash, or seizure and rhabdomyolysis (in a subject receiving high dose methadone chronically).

-- No dose-limiting toxicities were identified across the range of study doses.

Genetic Sequencing

NS5B sequencing was performed on 36 subjects (11 on peg-IFN alone; 25 HCV- 796 and peg-IFN). Consistent with data from the Phase 1b study of HCV-796 as monotherapy, the only variant of importance detected in patients receiving HCV-796 was a C316Y variant known to have reduced susceptibility to HCV-796.

Baseline sequencing did not find any variation from wild type at this position. The C316Y variant was observed in 7 (28 percent) of patients on HCV- 796 plus peg-IFN, occurring less frequently than previously seen in patients receiving HCV-796 as monotherapy, and was not clearly associated with virologic response pattern. The clinical implication of this mutation, if any, will be evaluated in ongoing and future long-term studies.

About Hepatitis C

Hepatitis C is a blood-borne virus recognized as a major cause of chronic hepatitis worldwide. The World Health Organization estimates that 170 million persons worldwide are chronically

infected with HCV, and three to four million persons are newly infected globally each year. According to the U.S. Centers for Disease Control and Prevention (CDC), about four million people in the U.S., or 1.8 percent of the population, are infected with HCV.

Currently, there is no specific antiviral agent directed against HCV that is commercially available, and no vaccine for prevention of HCV infection. Several interferon (IFN) products are available worldwide, but there are substantial limitations to the use of these products when given as monotherapy or in conjunction with ribavirin in the treatment of chronic HCV infection. In addition to the relatively poor treatment response in patients infected with genotype 1 HCV, the most common strain in the U.S., Western Europe and Japan, the considerable side effects frequently associated with the use of IFN can lead to discontinuation of therapy in approximately 20 percent of patients.

About ViroPharma Incorporated

ViroPharma Incorporated is committed to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings.

ViroPharma commercializes Vancocin(R), approved for oral administration for treatment of antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains (for prescribing information, please download the package insert at

http://www.viopharma.com/docs/pulvules_pi.pdf).

ViroPharma currently focuses its drug development activities in viral diseases including cytomegalovirus (CMV) and hepatitis C (HCV). For more information on ViroPharma, visit the company's website at <http://www.viopharma.com> .SOURCE ViroPharma Incorporated