

HCV ADVOCATE WEEKLY NEWS REVIEW

Review of HCV, HBV and HIV/HCV Coinfection Related News and Highlights

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April 26th, 2007

Three Studies Presented at 43rd EASL Strongly Indicate Better Efficacy for PEGASYS in Curing Hepatitis C

<http://www.presseportal.de>

Basel, Switzerland (ots/PRNewswire) - - Roche Also Provides Comment on Results of "IDEAL" Trial

Roche today announced that compelling new data from three studies indicate that chronic hepatitis C patients who received PEGASYS(R) (peginterferon alfa-2a) plus COPEGUS(R) (ribavirin) had a greater chance of being cured of their disease than those who received combination therapy with another pegylated interferon and ribavirin. Results from the studies were presented this week at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL) in Milan, Italy.

Ascione, et al: A Prospective, Randomised, Investigator-Initiated Head-to-Head Trial

Results of this independently-conducted study(1) were presented by Professor Antonio Ascione, Director of the Department of Gastroenterology Liver Unit at Cardarelli Hospital in Naples, Italy, in the oral late-breaker session at EASL. It is a prospective, randomised, investigator-initiated head-to-head trial designed to directly compare Pegasys with peginterferon alfa-2b, each in combination with ribavirin. Enrolling 320 patients in Italy, the study randomised patients to receive either Pegasys 180 mcg/week or peginterferon alfa-2b 1.5 mcg/kg/week. Importantly, patients received equivalent starting doses of ribavirin (either 1,000 or 1,200 mg ribavirin per day based on body weight), and the process for ribavirin dose reduction was the same for all patients.

The results showed that 68.7% of patients on Pegasys achieved a cure, compared to only 54.4% of patients on peginterferon alfa-2b (p=0.008). Furthermore, in genotypes 1 and 4 - the most difficult-to-treat patient group - Pegasys achieved a cure in 54.8% of patients, compared to only 39.8% on peginterferon alfa-2b (p=0.04). Side effects were similar, although there were more

withdrawals for side effects in the peginterferon alfa-2b group.

T. Witthoef, et al: Hepatitis C Treatment in Real-Life PRACTICE in Germany

Another study presented at EASL, called PRACTICE, analysed the response of 3,470 patients to hepatitis C treatment between 2000 and 2007 in 23 German treatment centres with a high volume of patients(2). Patients were matched by key baseline characteristics, as well as by those who received a similar cumulative ribavirin dose. Among these matched pairs, significantly more patients treated with Pegasys plus Copegus achieved a cure compared to those treated with peginterferon alfa-2b and ribavirin (59.3% vs. 53.0% (p = 0.008)).

Craxi, et al: PROBE Compares the Pegylated Interferons

PROBE, an observational study, was designed to prospectively evaluate the efficacy of the pegylated interferons in real-life practice(3). The study enrolled 1,351 patients with genotype 1 virus at 167 treatment centres in Italy. Again, the trial found a greater chance of a cure in patients treated with Pegasys combination therapy compared to those treated with peginterferon alfa-2b combination therapy (41% versus 34%, respectively (p=0.004)).

"We are pleased that three separate studies presented at EASL all indicate that Pegasys provided patients with a better chance for a cure. These results will help physicians and patients make an informed choice of treatment for chronic hepatitis C. In fact, in all the major markets, an increasing proportion of physicians and patients have selected Pegasys for their therapy in the last several months," said Dr Ueli Fankhauser, global leader for Pegasys at Roche. "We are committed to further advancing the treatment of hepatitis C. Reflecting Roche's leadership in this area, our comprehensive clinical trials programme aims to optimise treatment with Pegasys and Copegus in the hope of bringing treatment success to even more patients."

Roche Comments on Schering-Plough "IDEAL" Study

Roche reiterated its position on the Schering-Plough sponsored trial called "IDEAL," results of which were also presented at EASL. Clear biases(4) in the design of this study prevent any direct comparison of the pegylated interferons. These biases include:

- different blinding for the Pegasys arm,
- different ribavirin starting doses,
- a different ribavirin dose reduction protocol, and
- unequal thresholds for the use of erythropoietin-stimulating agents.

Despite these biases, it is interesting to note that significantly more patients in the Pegasys arm had an undetectable viral load while on treatment ("end of treatment" response)(5). This is a promising finding, given that the likelihood for a cure in these patients is even higher when modern treatment principles, such as extending the treatment period beyond 48 weeks, are applied. In addition, the study failed to show a benefit for weight-based dosing of peginterferon alfa-2b (which requires dose adjustments based on a patient's body weight) vs. Pegasys, which is given as a fixed dose regardless of a patient's body weight.

Roche's R1626, First-in-Class Hepatitis C Polymerase Inhibitor, Demonstrates Impressive End-of-Treatment Response in Phase IIa Study

<http://www.finanznachrichten.de>

Basel, Switzerland (ots/PRNewswire) -

- R1626 Also Shows a High Barrier to the Development of Resistance

Roche's investigational treatment for hepatitis C, R1626, has shown an impressive end-of-treatment response rate when given in combination with PEGASYS(R) (peginterferon alfa-2a) and COPEGUS(R) (ribavirin).

After 4 weeks of treatment with this triple combination, followed by 44 weeks of Pegasys and Copegus, levels of the hepatitis C virus (HCV) were undetectable in 84% of patients infected with genotype 1 virus. This was higher than in patients treated with Pegasys and Copegus alone for the entire 48-week treatment period (65%).(1) These new data were presented in a late-breaker oral session at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL), being held in Milan, Italy.

Discovered and developed at Roche, (News/Aktienkurs) R1626 is a potent polymerase inhibitor which belongs to a new generation of treatments that directly inhibit replication of HCV. It is the most advanced polymerase inhibitor in development.

"These results demonstrate that R1626 holds significant promise to potentially increase the number of hepatitis C patients who can be successfully treated. It is particularly interesting that R1626, a polymerase inhibitor, is demonstrating a higher end-of-treatment response rate than current HCV protease inhibitors in development, together with a high barrier to the development of resistance," said Dr David Nelson, Director of Hepatology and Liver Transplantation at the University of Florida, Gainesville, Florida, USA. "Since most patients responded very early in treatment with R1626, we expect excellent SVR rates that improve significantly on those achieved with the current standard of care. I look forward to SVR data from this Phase IIa study, and to results of the ongoing Phase IIb study."

Patients in this Phase IIa study will be followed for an additional 24 weeks with no treatment to determine the rate of sustained virological response (SVR), indicating a cure.

Rapid development of R1626 - a Large Phase IIb Study is Now Fully Enrolled

A large Phase IIb study with R1626 was initiated in November 2007 to define the optimal dose of R1626, in combination with Pegasys and Copegus. This Phase IIb trial, called POLI 1, is now fully enrolled with approximately 500 patients.

More About the Phase IIa Study and End-of-Treatment Results Presented at EASL

The Phase IIa study is a multicenter trial that enrolled 104 patients with genotype 1 HCV, who had not previously received treatment. Its primary endpoint was to evaluate the 4-week efficacy and safety of combining R1626 with Pegasys alone or with Pegasys plus Copegus, in comparison to a current HCV standard of care, Pegasys plus Copegus.

Patients were randomised into the following treatment groups:

- Group A: R1626 1,500 mg twice a day plus Pegasys 180 mcg weekly for 4 weeks
- Group B: R1626 3,000 mg twice a day plus Pegasys 180 mcg weekly for 4 weeks
- Group C: R1626 1,500 mg twice a day plus Pegasys 180 mcg weekly plus Copegus 1,000/1,200 mg daily for 4 weeks
- Group D (standard of care group): Pegasys 180 mcg weekly plus Copegus 1,000/1,200 mg daily for 4 weeks

Following the 4 weeks of treatment in this study, all patients received Pegasys 180 mcg weekly plus Copegus 1,000/1,200 mg daily for an additional 44 weeks to complete the 48-week trial.

The study found(1):

- Data collected at 4 weeks showed that patients receiving the triple combination (Group C) had a mean decrease in viral load of 5.2 log₁₀ from baseline, indicating a robust and rapid virological response
- At week 48, HCV was undetectable in 84% of patients receiving the triple combination R1626 1,500 mg BID + Pegasys + Copegus, compared with 65% of patients treated with Pegasys and Copegus alone
- A higher incidence of grade 4 neutropaenia was reported in the R1626 treatment arms during the 4-week treatment period; however, after stopping treatment with R1626, absolute neutrophil counts returned to the levels typically seen with patients taking standard of care alone

R1626 - a High Barrier to the Development of Resistance

In a separate oral presentation at EASL, it was reported that R1626 continues to present a high barrier to the development of viral resistance. Resistance is a serious concern in hepatitis C treatment, as resistant viruses have emerged in patients early on in treatment with protease inhibitors. Resistance to R1626 has not been yet been identified, after either 2 weeks of R1626 monotherapy, or after 4 weeks in patients treated with R1626 in combination therapy.(2)

Vertex Announces Positive Interim Results with Telaprevir-based Therapy in Genotype 1 Chronic Hepatitis C Patients who Failed to Achieve S SVR with a previous pegylated interferon and ribavirin treatment regimen.

<http://www.infobolsa.es>

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 “-0- *T Prior Virologic Response in Interim HCV RNA Results in Patients Phase 2 control arm Reaching Week 4, 8 and 12 Assessments studies”

April 27th, 2007

Hepatitis C clinics needed in state

<http://newsok.com>

By Ted Bader, M.D.

Never in the history of medicine has a curable chronic infectious disease causing so many deaths been so ignored by government.

Hepatitis C infects more than 80,000 Oklahomans and often leads to end-stage liver disease requiring liver transplantation or to liver cancer. Deaths due to hepatitis C are underreported and it is likely at least one Oklahoman is dying every day from the consequences of this infection. The majority of those infected are not in the drug culture, but rather everyday citizens. The most famous Oklahoman to die from hepatitis C was Mickey Mantle.

What is shameful here is that hepatitis C can be cured 50 percent of the time with one-year treatment with peginterferon and ribavirin. "Cure" is a real term as the first patients who cleared virus in interferon trials 25 years ago have remained undetectable for virus. When patients are cured, they feel dramatically better, their health care costs plummet and their risk of liver cancer drops dramatically.

Last year, the state of Oklahoma spent \$40,000 for all purposes against hepatitis C. The federal government gave \$80,000 to support a hepatitis C control nurse at the state Health Department. In contrast, for a noncurable viral illness, HIV, which has one-quarter the number of patients of hepatitis C, the state spent \$1.6 million that was matched with about \$3.5 million by the federal government.

Very few providers are available who are willing and able to treat hepatitis C because of the low financial reimbursement from insurance companies and the associated liver disease that often complicates their management.

Oklahoma is one of the few states that doesn't have a clinic devoted to the treatment of hepatitis C. The finances of such a clinic are tenuous and good planning envisions a partnership of commercial insurance, public health and legislative support.

What can an interested person do? There is a supplemental \$1 million appropriation item in the public health appropriations bill in the current legislative session to assist in the opening of the aforementioned hepatitis C clinic. The funds would be directed through the state public health department. People can call their state senator or representative and tell them of their support.

This appropriation should not be taken from the proposed budget for the public health department, as it makes no sense to rob Peter to pay Paul. Medical economists have calculated a 20-to-1 return in health care cost savings for every dollar spent on treatment of hepatitis C. It is quite reasonable to postulate that \$1 million spent this year will save \$5 million to \$10 million in the state Medicaid budget five to 10 years from now.

Bader is director of liver diseases for the VA Medical Center and the OU Health Sciences Center. The views expressed here do not necessarily reflect the position of the Veteran's Administration or the University of Oklahoma.

Medical marijuana patients face transplant hurdles

<http://ap.google.com>

By GENE JOHNSON

SEATTLE (AP) — Timothy Garon's face and arms are hauntingly skeletal, but the fluid building up in his abdomen makes the 56-year-old musician look eight months pregnant.

His liver, ravaged by hepatitis C, is failing. Without a new one, his doctors tell him, he will be dead in days.

But Garon's been refused a spot on the transplant list, largely because he has used marijuana, even though it was legally approved for medical reasons.

"I'm not angry, I'm not mad, I'm just confused," said Garon, lying in his hospital bed a few minutes after a doctor told him the hospital transplant committee's decision Thursday.

With the scarcity of donated organs, transplant committees like the one at the University of Washington Medical Center use tough standards, including whether the candidate has other serious health problems or is likely to drink or do drugs.

And with cases like Garon's, they also have to consider — as a dozen states now have medical marijuana laws — if using dope with a doctor's blessing should be held against a dying patient in need of a transplant.

Most transplant centers struggle with the how to deal with people who have used marijuana, said Dr. Robert Sade, director of the Institute of Human Values in Health Care at the Medical University of South Carolina.

"Marijuana, unlike alcohol, has no direct effect on the liver. It is however a concern ... in that it's a potential indicator of an addictive personality," Sade said.

The Virginia-based United Network for Organ Sharing, which oversees the nation's transplant system, leaves it to individual hospitals to develop criteria for transplant candidates.

At some, people who use "illicit substances" — including medical marijuana, even in states that allow it — are automatically rejected. At others, such as the UCLA Medical Center, patients are given a chance to reapply if they stay clean for six months. Marijuana is illegal under federal law.

Garon believes he got hepatitis by sharing needles with "speed freaks" as a teenager. In recent years, he said, pot has been the only drug he's used. In December, he was arrested for growing marijuana.

Garon, who has been hospitalized or in hospice care for two months straight, said he turned to the university hospital after Seattle's Harborview Medical Center told him he needed six months of abstinence.

The university also denied him, but said it would reconsider if he enrolled in a 60-day drug-treatment program. This week, at the urging of Garon's lawyer, the university's transplant team reconsidered anyway, but it stuck to its decision.

Dr. Brad Roter, the Seattle physician who authorized Garon's pot use for nausea, abdominal pain and to stimulate his appetite, said he did not know it would be such a hurdle if Garon were to need a transplant.

That's typically the case, said Peggy Stewart, a clinical social worker on the liver transplant team at UCLA who has researched the issue. "There needs to be some kind of national eligibility criteria," she said.

The patients "are trusting their physician to do the right thing. The physician prescribes marijuana, they take the marijuana, and they are shocked that this is now the end result," she said.

No one tracks how many patients are denied transplants over medical marijuana use.

Pro-marijuana groups have cited a handful of cases, including at least two patient deaths, in Oregon and California, since the mid-to-late 1990s, when states began adopting medical marijuana laws.

Many doctors agree that using marijuana — smoking it, especially — is out of the question post-transplant.

The drugs patients take to help their bodies accept a new organ increase the risk of aspergillosis, a frequently fatal infection caused by a common mold found in marijuana and tobacco.

But there's little information on whether using marijuana is a problem before the transplant, said Dr. Emily Blumberg, an infectious disease specialist who works with transplant patients at the University of Pennsylvania Hospital.

Further complicating matters, Blumberg said, is that some insurers require proof of abstinence, such as drug tests, before they'll agree to pay for transplants.

Dr. Jorge Reyes, a liver transplant surgeon at the UW Medical Center, said that while medical marijuana use isn't in itself a sign of substance abuse, it must be evaluated in the context of each patient.

"The concern is that patients who have been using it will not be able to stop," Reyes said.

Dale Gieringer, state coordinator for the California chapter of NORML, the National Organization for the Reform of Marijuana Laws, scoffed at that notion.

"Everyone agrees that marijuana is the least habit-forming of all the recreational drugs, including alcohol," Gieringer said. "And unlike a lot of prescription medications, it's nontoxic to the liver."

Reyes and other UW officials declined to discuss Garon's case.

But Reyes said that in addition to medical concerns, transplant committees — which often include surgeons, social workers, and nutritionists — must evaluate whether patients have the support and psychiatric health to cope with a complex post-operative regimen for the rest of their lives.

Garon, the lead singer for Nearly Dan, a Steely Dan cover-band, remains charged with manufacturing weed. He insists he was following the state law, which limits patients to a "60-day supply" but doesn't define that amount.

"He's just a fantastic musician, and he's a great guy," said his girlfriend, Leisa Bueno. "I wish there was something we could do legally. ... I'm going to miss him terribly if he passes."

On the Net:

- United Network for Organ Sharing: <http://www.unos.org>
- Garon performing his song "Goodbye Baby":
http://www.youtube.com/watch?vUJDihYn_fJA

Interim Results From Boceprevir Phase II Study In Genotype 1 Treatment-Naive Hepatitis C Patients Presented At EASL

<http://www.medicalnewstoday.com>

Schering-Plough Corporation (NYSE: SGP) reported that results from a planned interim analysis of an ongoing Phase II study of boceprevir, its investigational oral hepatitis C protease inhibitor,

in 595 treatment-naive patients with chronic hepatitis C virus (HCV) genotype 1 were presented at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL). The ongoing study evaluates boceprevir in 28-week and 48-week treatment regimens.

In a 28-week treatment regimen in which patients received 4 weeks of PEGINTRON(TM) (peginterferon alfa-2b) and REBETOL(R) (ribavirin, USP) prior to the addition of boceprevir (800 mg TID), the rate of sustained virological response at 12 weeks after the end of treatment (SVR 12) was 57 percent (ITT).(1-3) Importantly, this treatment regimen provided an indication of early predictability of response, with patients who had undetectable virus (HCV-RNA) in plasma after 4 weeks of boceprevir treatment achieving an SVR 12 rate of 86 percent.

"These interim results are very encouraging, especially given the response seen with a shorter course of therapy in a difficult-to-treat patient population," said principal investigator Paul Kwo, M.D., associate professor of medicine and medical director, liver transplantation, Department of Medicine, Division of Gastroenterology/Hepatology, Indiana University School of Medicine, Indianapolis, who presented the data. "Boceprevir has been well tolerated by patients in this study, including in the longer duration treatment arms, and we look forward to further results from this ongoing study."

Overall, 77 percent of the 595 patients in the study were enrolled in the United States. African-Americans represent 16 percent of the patients enrolled and 7 percent of patients in the study are cirrhotic.

In the ongoing study, known as HCV SPRINT-1 (HCV Serine Protease Inhibitor Therapy-1), boceprevir (800 mg TID) is being evaluated in three treatment regimens: 4 weeks of PEGINTRON (1.5 mcg/kg once weekly) and REBETOL (800-1400 mg daily based on patient weight) therapy followed by the addition of boceprevir to the combination for 24 or 44 weeks (totaling 28 or 48 weeks of treatment); boceprevir in combination with PEGINTRON and REBETOL at the doses described above for 28 or 48 weeks (triple combination); and boceprevir in combination with PEGINTRON and low-dose REBETOL (400-1000 mg daily) for 48 weeks, compared to a control of PEGINTRON (1.5 mcg/kg once weekly) and REBETOL (800-1400 mg daily based on patient weight) alone for 48 weeks (an approved treatment regimen). The primary endpoint of the study is sustained virologic response after 24 weeks of follow up.

During a late-breaker oral presentation at EASL, Dr. Kwo presented interim results for the two 28-week boceprevir arms of the study. For patients receiving 4 weeks of PEGINTRON and REBETOL therapy prior to the addition of boceprevir, SVR 12 was 57 percent (59/103), compared to 55 percent (59/107) for patients in the boceprevir triple combination arm. For patients in these two boceprevir arms who had undetectable virus (HCV-RNA) after 4 weeks of boceprevir treatment (RVR), the SVR 12 rates were 86 percent (53/62) and 74 percent (31/42), respectively. SVR 12 rates are not yet available for patients in the 48-week boceprevir arms or the 48-week control arm, as treatment of these patients is ongoing.

Safety data from the study showed that the most common adverse events reported in the boceprevir arms were fatigue, anemia, nausea and headache. No increase in skin adverse events (rash or pruritus) beyond what was seen in the PEGINTRON and REBETOL control arm was observed. Treatment discontinuations due to adverse events were between 11 and 15 percent for patients in the boceprevir arms, compared to 8 percent for the control arm.

Early response rates at week 4 (RVR) and week 12 (EVR) of boceprevir treatment were increased for patients who received 4 weeks of PEGINTRON and REBETOL therapy prior to the administration of boceprevir (62 and 79 percent, respectively), compared to patients in the triple combination (38 and 69 percent) and control (8 and 34 percent) arms, respectively. In the 28-week boceprevir arms, these patients also had a reduction in viral breakthrough compared to patients in the triple combination arm (4 vs. 7 percent, respectively).

"The results seen with this novel treatment paradigm will influence the design of our future clinical studies, as we plan to consider RVR at week 4 of boceprevir treatment as the criterion for determining which patients can receive a shorter course of boceprevir therapy and which patients should continue treatment for 48 weeks," said Robert J. Spiegel, M.D., chief medical officer and senior vice president, Schering-Plough Research Institute. "Additionally, this strategy has the potential to reduce the likelihood of the development of resistance by identifying patients who are responders to interferon and ribavirin prior to their receiving a protease inhibitor."

The rationale for this novel treatment regimen is based on the fact that both PEGINTRON and REBETOL reach steady-state concentrations by week 4, so patients have the protease inhibitor added at a time when the backbone drug levels have been optimized. In addition, the patient's immune system will have been activated and primed by PEGINTRON at the time that boceprevir is added to the regimen. This approach may minimize the period of time when there is a "functional monotherapy" with a direct antiviral, potentially reducing the likelihood for the development of resistance.

The HCV SPRINT-1 study is currently ongoing at sites across the United States, Canada and Europe. Final results from the study are anticipated to be available in early 2009, and will be submitted for presentation at an appropriate medical meeting.

Gilead Announces 72-Week Data From Two Pivotal Phase III Studies Evaluating Viread(R) for the Treatment of Chronic Hepatitis B

<http://www.infobolsa.es>

Resistance surveillance through week 72 did not detect any tenofovir-associated mutations.

Two patients exhibited loss of viral response as defined by study investigators with documented non-adherence and were evaluated via genotypic analysis.

Neither developed mutations associated with Viread resistance.

Study 103 Study 103 is a multi-center, randomized, double-blind Phase III clinical trial evaluating the efficacy, safety and tolerability of Viread among treatment-naïve patients with HBeAg-positive chronic hepatitis B.

Two hundred sixty-six patients were originally randomized in a 2:1 ratio to receive either Viread (300 mg once daily; n=176) or Hepsera (10 mg once daily; n=90).

Baseline characteristics were similar between patients in both study arms.

As with Study 102, after the completion of 48 weeks of randomized blinded therapy, all eligible patients were offered open-label Viread monotherapy.

At week 72, 79 percent of patients who were originally randomized to receive Viread had a virologic response below 400 copies/mL.

Among Hepsera-treated patients who switched to Viread after Week 48, 76 percent achieved HBV DNA below 400 copies/mL by week 72.

Through week 72, viral suppression was maintained among all patients who switched to Viread and who were previously virologically controlled with Hepsera (n=12).

Additionally, rapid viral suppression to less than 400 copies/mL was achieved by week 72 in 78 percent of viremic Hepsera-treated patients who switched to Viread after week 48.

At week 72, normal ALT levels were observed in 77 percent of patients who were originally randomized to receive Viread and 61 percent of Hepsera-treated patients who switched to Viread.

Among patients for whom seroconversion data was available through week 64, 26 percent of patients who were originally randomized to receive Viread "e" antigen seroconverted, compared to 21 percent of Hepsera-treated patients who switched to Viread.

Seroconversion is defined as both the disappearance of the hepatitis B "e" antigen (HBe-antigen negative), a marker of HBV replication, and the appearance of antibodies specific for this antigen (HBe-antibody positive).

In addition, 5 percent of patients who were originally randomized to receive Viread compared to zero percent of Hepsera-treated patients who switched to Viread after week 48 experienced "s" antigen (HBsAg) loss (p=0.004), which can indicate that a patient has cleared chronic hepatitis B infection.

As with Study 102, Viread was generally well tolerated.

At week 72, treatment-related serious adverse events occurred in 4 percent of patients who were originally randomized to receive Viread and 7 percent of Hepsera-treated patients.

The incidence of Grade 4 laboratory abnormalities was comparable in each arm (12 percent versus 11 percent).

Grade 3 laboratory abnormalities, excluding ALT elevations, were 18 and 10 percent, respectively.

Grade 3 ALT elevations were 15 and 10 percent, respectively, in the Viread and Hepsera arms.

No patient had a confirmed creatinine clearance of less than 50 mL/minute.

The most common adverse reactions among patients receiving Viread for chronic hepatitis B in Studies 102 and 103 were headache, diarrhea, vomiting, abdominal pain, nausea, abdominal

distension, flatulence, ALT increase and fatigue.

In terms of resistance surveillance, between weeks 48 and 72 no patients experienced a loss of virologic response.

Additional Oral Presentations at EASL Three additional oral presentations, one of which features the first data to be presented from Study 106, will be highlighted at EASL.

Study 106 is an ongoing, randomized, double-blind Phase II study of individuals with chronic hepatitis B infection randomized in a 1:1 ratio

April 28th, 2007

Analysts see Vertex as top hepatitis C drug developer

<http://biz.yahoo.com>

Analysts say Vertex Pharmaceutical's hepatitis C drug candidate poised to dominate the market

NEW YORK (AP) -- Vertex Pharmaceutical Inc.'s hepatitis C drug telaprevir will likely dominate the market and its rival, Schering-Plough Corp.'s boceprevir, according to several analysts.

The companies presented dueling data on each of their developing hepatitis C drugs at the 43rd annual meeting of the European Association for the Study of the Liver last week. Analysts said telaprevir showed the most promise.

"We maintain that boceprevir should eventually be approved but its potential to garner significant market share is unclear due to an inferior profile and uncertainties about the timing of Phase III (clinical trial) initiation," Cowen and Co. analyst Steve Scala said in a note to Schering-Plough investors.

On Saturday, Schering-Plough said an interim analysis of midstage study results showed the drug candidate prompted an immune response in patients. But, earlier in the week, Vertex showed that telaprevir prompted a higher response rate.

"Following underwhelming competitor clinical data we believe Vertex's telaprevir will play a dominant role in the treatment of hepatitis C," Wachovia Capital Markets analyst George Farmer said in a note to Vertex investors.

Hepatitis C is a blood infection that can cause liver inflammation and possibly liver cancer. Both companies plan to move their respective drug candidates into late-stage development, where effectiveness will be tested on larger groups of patients. Though Wall Street is leaning toward telaprevir as the market leader, it is the Phase III, or late-stage, study that will really prove a drug's effectiveness.

Though telaprevir's recent results set it up as the likely top drug, said Oppenheimer & Co, analyst Dr. Brian Abrahams, boceprevir could still pose a threat.

"We believe boceprevir's clear activity and reasonable safety do warrant further development," he said, adding that the Schering-Plough data substantially reduce, but do not completely eliminate, a long-term competitive overhang on Vertex.

Shares of Kenilworth, N.J.-based Schering-Plough Corp. rose 8 cents to \$18.72, while shares of Cambridge, Mass.-based Vertex Pharmaceuticals Inc. rose 15 cents to \$25.87 in afternoon trading.

Silver Nano-Particles Can Rein In Replication Of Hepatitis B Virus

<http://www.bernama.com>

HONG KONG, April 28 (Bernama) -- Silver nano-particles with an average diameter of 5 to 50 nanometers, can rein in the in vitro replication of hepatitis B viruses (HBV) through direct interaction with its DNA and viral particles, researchers said Monday.

Lei Lu, a Ph.D. candidate at the Hong Kong University, said his team found that the ultra-tiny silver particles could reduce the extracellular DNA formation of HBVs by over 50 percent, and could check their intracellular RNA formation, too.

"Silver nano-particles have special properties such as larger active surface and porosity so that they can easily bind with small molecules," China's XINHUA news agency quoted Lu as saying, referring to a hypothetical explanation they had put forward on the new antiviral mechanism.

"The finding provides a new direction for developing new anti-HBV drugs, with nano-particles used as drug carrier to enhance the antiviral efficacy while minimizing the undesirable side effects," Lu told a press conference Monday.

The young researcher said there are currently only two kinds of drugs approved for treating chronic HBV infection, namely immunomodulators and nucleoside analogues. But their uses are affected by side effects and drug-resistant mutations.

Hepatitis B is one of the worst killers as it chronically infects over 400 million people worldwide, with certain developing countries and regions hit hardest.

Lu said silver nano-particles have an additional distinct advantage. It is unlikely that HBV can become resistant to silver nano-particles because the interaction is determined by the physiochemical properties of the tiny particles.

The study on silver nano-particles is still in the laboratory stage and any drugs it may lead to are still 3 to 5 years away from clinic use, Lu said.

The study, conducted jointly by researchers at the Department of Medicine and the Department of Chemistry of the Hong Kong University, has been published in the March issue of *Antiviral Therapy*, the world's leading antiviral research journal.

Team develops safe, effective RNA interference technique

<http://www.physorg.com>

A team of researchers from MIT and Alnylam Pharmaceuticals has developed safe and effective methods to perform RNA interference, a therapy that holds great promise for treating a variety of diseases including cancer and hepatitis.

"RNA interference is a tool that has a lot of people excited, and one reason for the excitement is that we hope it will provide a new method to control almost any gene in your body," said Daniel Anderson of the David H. Koch Institute for Integrative Cancer Research at MIT and the senior author of a paper on the work appearing as the cover story in *Nature Biotechnology* today.

Scientists see RNA interference (RNAi) as a way to turn off specific disease-causing genes. Despite this potential, researchers studying the technique have been stymied by one major problem: How to deliver RNAi agents to target tissues.

Now, the MIT/Alnylam team has developed a library of new molecules that successfully delivered RNA interference agents in several animals, including mice, rats and cynomolgus monkeys. The team hopes to test the delivery materials in human clinical trials within the next few years.

RNAi works by disrupting the flow of genetic information from a cell's nucleus to the protein-building machinery of the cell. Gene expression can be turned on or off by interfering with messenger RNA, which carries that information.

One way to deliver RNAi is to package siRNA (short interfering RNA) inside nanoparticles that can deliver it directly to the target cell.

In previous studies, lipids (fat-soluble molecules such as fats, waxes and cholesterol) have shown promise as RNAi delivery agents. However, only a limited number of different materials had been developed when those studies were conducted.

Using a new synthesis scheme that allows for high-speed production, the researchers created a huge library of lipid-like molecules called lipidoids. A major advantage of these chemical methods is that they facilitate production of a large variety of different molecules, which could be customized for different RNAi therapies and drug-delivery problems.

The MIT team found several lipidoids that successfully delivered siRNA to the liver, which may provide a therapy for diseases ranging from cancer to viral infection, Anderson said. They also demonstrated siRNA delivery to the lungs, where it blocked genes expressed by respiratory syncytial virus that had infected the lungs. The lipidoids were also able to deliver siRNA to immune cells called macrophages.

In some cases, the effects of a single RNAi injection lasted up to four weeks. The researchers also showed that they could block two genes at once, raising the possibility of treating diseases that involve multiple genes.

The delivery system also proved effective with another type of RNA interference, which

involves disrupting microRNA (very short strands of RNA that help control gene expression).

"For the first time, we've got a lot of formulations to choose from," Anderson said. "In the next five years, we expect to push this technology forward in a number of different clinical and drug-delivery applications."

The first author of the paper is Akin Akinc, who received a PhD in chemical engineering from MIT in 2003 and is now at Alnylam. Andreas Zumbuehl, now at the University of Geneva; MIT students Michael Goldberg, Elizaveta Leshchiner, Valentina Busini, Sergio Bacallado, David Nguyen and Jason Fuller; and Institute Professor Robert Langer are also authors of the paper.

Source: MIT

April 29th, 2007

Gays, Straights Show Similar Rates of Hep C Infection

by Kilian Melloy

<http://www.edgeboston.com>

EDGE Contributor

One finding that came out of a conference of sexual health experts in London last week: HIV-negative gay men do not show a greater incidence of hepatitis C infections.

However, reported aidsmap.com on an online story posted Apr. 28, individuals of any sexuality living with HIV do seem to show a greater tendency toward hepatitis C than the general population.

Hepatitis C is a serious liver disease that can be communicated through blood-to-blood contact, as with sharing needles or receiving infected blood via a transfusion. Though hepatitis C can be managed, and sometimes even cured, there is no vaccine; long-term prospects of living with the disease can include scarring of the liver (cirrhosis) or liver cancer.

The finding was the result of a study undertaken by the University college Hospital's Center for Sexual Health. The center made hepatitis C tests available to all male clients at its GUM, or sexual health, clinic for a one-year period from March, 2007, to March of this year.

The study was triggered by an increase of hepatitis C among HIV-positive gay men. The researchers wished to find out whether HIV-negative gay men were similarly affected by the rise in new infection rates.

The study indicated that HIV-negative gay men had not been affected, according to Dr. Jo Tuner, who on Apr. 25 explained the study and its results to those attending the 14th British HIV Association (BHIVA) Conference, reported aidsmap.com.

During the year-long study, the clinic served 10,204 men, the [aidsmap](http://aidsmap.com) article said, and 44 percent of those (4,554) agreed to the hepatitis C test. The study consisted of test results from 4,472 men, of varying sexual orientations and national origins. Some past or current hypodermic needle drug-users (108) were also part of the group that was tested; of those, 77 were also gay

men.

The demographics skewed somewhat to the gay population (58 percent of those who took the hepatitis C test were gay), and predominantly Caucasian (71 percent). 1,032 of those tested, or 23 percent, were living with HIV.

The latest results from the study showed that 114 of the men tested had been infected with hepatitis C. Of those, 97 were known already; 17 cases had not been previously known.

Among those living with HIV (regardless of sexual orientation), the hepatitis C rate was 82 individuals, or 9.3 percent. HIV-positive gay men fared no worse than straight men, with a rate of hepatitis C infection of 9.25 percent.

Among HIV negative men, the general rate of hepatitis infection was just over one half of one percent (0.51); HIV-negative gay men showed a rate just slightly lower, with 0.49 percent. One case of hepatitis infection was documented in a straight patient whose HIV status was not known.

Out of the 17 cases of hepatitis infection that had previously been unknown, only ten cases seemed to be what is classified as "chronic." While hepatitis C is a serious disease, some individuals can become free of the disease with treatment; three of the 17 cases showed antibodies for the disease but did not seem to be currently infected. The other four seemed to have contracted the disease only recently.

Among the ten chronic sufferers there were six men living with HIV; three of those were needle users. Two cases were identified as gay men who were HIV-negative, and one case was of a needle user who was also clear of the HIV virus.

Of the four men who seemed to have contracted the disease recently, three were living with HIV and one was negative for HIV--though, perhaps tellingly, that man was on a preventative regimen of anti-retrovirals as a means of staving off HIV infection from his partner, who was reportedly positive.

The overall results (minus the results for needle users) showed that gay and straight men living with HIV had virtually the same rate of hepatitis C infection (7.5 percent among the gay men of the study versus 6.5 percent of the straight men), as did gay and straight men who were HIV negative (0.4 percent among gay men and 0.2 percent among straight men). The main factor seemed not to be sexuality, but HIV status.

Dr. Turner offered an explanation as to how HIV positive men came to have a higher instance of hepatitis infection, saying that the men may have withheld information as to any history of needle usage, aidsmap.com reported.

Kilian Melloy reviews media, conducts interviews, and writes commentary for EDGEBoston, where he also serves as Assistant Arts Editor.

Hepatitis B an issue 'too hot to handle'

<http://www.theaustralian.news.com.au>

Adam Cresswell, Health editor

PEOPLE with the incurable viral illness hepatitis B are missing out on vital services because the disease is seen as a racial hot potato, according to a top Australian virologist who criticised the Government for failing to tackle the problem.

Stephen Locarnini, director of the World Health Organisation's Collaborating Centre for Virus Reference and Research in Melbourne, said at an international meeting of liver specialists in Italy that while HIV and hepatitis C benefited from having patient advocacy groups lobbying, hepatitis B was largely ignored despite affecting almost 200,000 Australians - more than 10 times as many as HIV, and comparable to hepatitis C.

However, far from being evenly distributed across the Australian population, patients affected by the hepatitis B virus were heavily concentrated in specific ethnic groups.

Professor Locarnini told The Australian that not only did government health bureaucrats see the issue as radioactive for that reason, but the communities most affected were also uneasy with attempts to highlight the problem in case that suggested to Australians at large that the minorities were riddled with an incurable and communicable disease.

As a result, the disease received a fraction of the funding of the better-recognised viral illnesses, and patients had more trouble accessing services and had to pay more for them when they could get them.

"The bureaucracy is of the view that the vaccine will eventually control the disease, so why bother (with effective treatment programs)?" Professor Locarnini said. "It's an ethnic issue - the bureaucrats are very nervous about dealing with it ... because it's a race issue, the Asians don't want advocacy.

"They don't want people to say 'Let's champion the Asians, they have hep B' - that's the last thing they want."

Hepatitis B is preventable with a vaccine, but the vaccine cannot root out existing infections. Although 95per cent of infections in adults will be cleared naturally, children are less able to shake it off. The virus causes an acute illness that can cause jaundice but the real problem is that chronic infection can lead to cirrhosis and liver cancer.

About 10 per cent of Asian and Mediterranean people are thought to be infected, as are 6 to 8 per cent of eastern Europeans and about 5 per cent of Africans.

Clinical Update - Debio 025 in Hepatitis C

<http://www.prnewswire.com>

Presentation of Phase IIa Efficacy Results

LAUSANNE, Switzerland, April 28 /PRNewswire/ -- Debiopharm Group (Debiopharm), a global independent biopharmaceutical development specialist focusing on serious medical conditions, particularly oncology, presented positive efficacy results of a phase IIa study with Debio 025, a selective cyclophilin (Cyp) inhibitor with a potent in-vitro and in-vivo anti-hepatitis C (HCV) effect. Data indicates that Debio 025 shows an important additive anti-HCV effect when co-administered with pegylated Interferon (Peg-IFN) alpha-2a to treatment-naïve HCV patients. Debiopharm presented these findings at the 43rd Annual Meeting of the European Association for the Study of the Liver, in Milan, Italy.

The double-blind, placebo-controlled study investigated different dose regimens of Debio 025 in combination with alpha-2a Peg-IFN 180 Mug/week in treatment-naïve chronic HCV mono-infected patients. Ninety patients were randomised to receive either of the following treatment regimens during 29 days: Peg-IFN with placebo; Peg-IFN with Debio 025 200 mg/day; Peg-IFN with Debio 025 600 mg/day; Peg-IFN with Debio 025 1000 mg/day; and Debio 025 1000 mg/day.

In patients with genotypes 1 and 4, at day 29, the HCV-RNA reduction was -4.6 log₁₀ IU/mL in the Peg-IFN with Debio 025 600 mg/day arm, and -4.8 log₁₀ IU/mL in the Debio 025 1000 mg/day arm. This was significantly different (p < 0.05) from the Peg-IFN with placebo, as well as the Debio 025 1000 mg/day monotherapy arms, in which the reduction in viral load was respectively -2.49 and -2.20. In these two arms, at day 29, the proportion of subjects with undetectable viral load was 25%. This number increased to 66% in the Peg-IFN with Debio 025 1000 mg/day group.

"To obtain these exciting results after an administration period of only one month is promising and demonstrates that Debio 025 will be a breakthrough in the treatment of HCV infections," said Kamel Besseghir, CEO of Debiopharm S.A. "This unique mechanism of action is the first alternative treatment to classic HCV therapies."

Debio 025

Debio 025 is a synthetic first-in-class Cyp inhibitor, being tested in humans as a potential anti-HCV drug. Debio 025 binds strongly to Cyp, host cell proteins thought to confer a replication advantage to HCV. Its potent inhibitory activity on the HCV replication was shown in preclinical studies.

Previous results of a phase Ib study demonstrate that Debio 025 monotherapy for 15 days induced a strong anti-HCV effect (3.6 log₁₀ reduction) in HIV-1/HCV co-infected patients. (*Hepatology*, Vol. 47, No 3, 2008, Flisiak et al. "The Cyclophilin Inhibitor Debio-025 Shows Potent Anti-Hepatitis C Effect in Patients Coinfected with Hepatitis C and Human Immunodeficiency Virus)."

About Debiopharm Group

Debiopharm Group is a global biopharmaceutical development specialist that in-licenses promising biologics and small molecule drug candidates. Debiopharm develops its products for global registration and maximum commercial potential for out-licensing to pharmaceutical partners for sales and marketing. Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs.

Founded in 1979 and headquartered in Lausanne, Switzerland, Debiopharm has developed three products with global combined sales in excess of US\$2.65 billion in 2007.

For more information on Debiopharm Group, please visit: <http://www.debiopharm.com>.

Former Patients React To Restraining Order In Hepatitis C Investigation

<http://www.ktnv.com>

Two doctors linked to the hepatitis C exposure are facing punishment for the first time.

The Board of Medical Examiners says they knew or should have known they were putting thousands at risk.

The State Attorney General has filed a temporary restraining order against Doctor Depak Desai and Eladio Carrera.

A judge could sign the restraining order as soon as Tuesday

Action News reporter Heather Klein explains the details.

The restraining order is for the doctor's medical licenses.

Both doctors face ten counts each including violating patient trust and medical malpractice.

Some of the doctor's former patients who are now positive for hepatitis C say this is a step in the right direction.

"He is the nastiest man I have ever met and those are nice words," explained former patient Shara Edwards.

Obviously, there is no love lost for Shara Edwards and her former doctor Dipak Desai.

"He violated every bit of our life from beginning to end to give us these diseases," said Edwards.

Shara tested positive for Acute Hepatitis C.

She is now one of Robert Eglet's clients and is suing Desai's practice.

While she is thankful the complaint charges include malpractice, violating patient trust and bringing the medical profession into disrepute is still not enough.

"I think he ought to have the blood tests and shots that I have to," said Edwards.

The complaint will not give her that but as Eglet explains it more than likely will keep Dipak Desai and Eladio Carrera from practicing.

"These are the surgeons, these are the captains of the ship over there, there the ones in charge of these surgeries and they are responsible for what is going on," said Eglet.

Now Shara says she is waiting for them to be held criminally responsible.

"I am hoping they can put him in jail along with his partners and everybody that worked in the clinic. They all need to go to jail," said Shara.

This is not a criminal complaint.

The State Board of Medical Examiners will present this before a hearing at which time the two doctors can fight for their license.

Stay tuned to Action News as we watch for new developments in the hepatitis C investigation.

Baraclude (Entecavir) Treatment Resulted In Greater Viral Load Suppression Compared to Adefovir at 96 Weeks In Antiviral-Naive Adult Chronic Hepatitis B E-Antigen Positive Patients

<http://pharmalive.com>

MILAN, Italy, April 26, 2008 /PRNewswire-FirstCall/ -- Bristol-Myers Squibb Company today announced new data from the E.A.R.L.Y. study (ETV-079), in which treatment of antiviral-naive adult chronic hepatitis B patients with Baraclude(R) (entecavir) resulted in greater long-term viral load reduction than adefovir at 96 weeks -- consistent with earlier 12-week results (primary endpoint). Suppression of viral load to undetectable levels is a measure of antiviral treatment response and is an important goal of chronic hepatitis B treatment. These data were presented today in Milan, Italy, at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL).

The E.A.R.L.Y. study is an open-label, randomized, viral kinetics study of 69 antiviral-naive chronic hepatitis B e-antigen (HBeAg) positive patients, comparing the antiviral activity of BARACLUDGE and adefovir. All patients in this study had a high viral load at study entry.(1) Of the 49 patients who remained in the study at 96 weeks, 79 percent (n=23/29) of BARACLUDGE-treated patients and 50 percent (n=10/20) of adefovir-treated patients achieved undetectable viral load.(2) The mean reduction in viral load from baseline in patients treated with BARACLUDGE was -7.82 log(10) copies/mL and was -5.96 log(10) copies/mL in patients treated with adefovir at week 96.

"BARACLUDGE maintains considerable antiviral efficacy through two years of treatment in this analysis," said Nancy Leung, M.D., of the Alice Ho Miu Ling Nethersole Hospital, Hong Kong, China. "This is important information for health care providers to consider when evaluating initial treatment options to suppress viral load in antiviral-naive chronic hepatitis B patients."

The safety profile was comparable between the treatment groups through 96 weeks. Three percent of patients receiving BARACLUDGE(R) (entecavir) (n=1) and 12 percent of patients receiving adefovir (n=5) experienced a serious adverse event. No deaths were observed in either treatment group. The most common adverse events occurring in greater than 10 percent of

patients in either treatment group were headache, nasopharyngitis, upper respiratory tract infection, influenza, pyrexia, urinary tract infection, cough, back pain, and diarrhea.

Data Results

By week 96, 22 of the 69 enrolled patients had discontinued the study. Of these, two patients receiving adefovir discontinued due to investigator-determined lack of treatment efficacy between the beginning of year two dosing and the 96-week analysis. The 96-week data reported below represent the results of the 49 patients who entered year two dosing (29 BARACLUDE-treated patients and 20 adefovir-treated patients), using the non-completer = failure (NC=F) method of analysis.

Week 96

- BARACLUDE-treated patients achieved a mean change in viral load of $-7.82 \log(10)$ copies/mL from baseline, and adefovir-treated patients achieved a mean change of $-5.96 \log(10)$ copies/mL.
- 79 percent (n=23/29) of BARACLUDE-treated patients and 50 percent (n=10/20) of adefovir-treated patients had undetectable viral load (HBV DNA less than 300 copies/mL, measured by the polymerase chain reaction or PCR assay).
- No BARACLUDE-treated patient (n=0/29) and 35 percent (n=7/20) of adefovir-treated patients had viral load greater than or equal to 10^5 copies/mL.
- 97 percent (n=28/29) of BARACLUDE patients achieved ALT normalization (ALT of less than or equal one time the upper limit of normal) compared with 85 percent (n=17/20) of adefovir-treated patients.
- 24 percent (n=7/29) BARACLUDE-treated patients achieved Hbe seroconversion compared with 25 percent (n=5/20) adefovir-treated patients.
- Six BARACLUDE(R) (entecavir)-treated patients and 16 adefovir-treated patients discontinued therapy prior to week 96.
- No BARACLUDE-treated patients and one adefovir-treated patient discontinued due to adverse events.
- No BARACLUDE-treated patients and six adefovir-treated patients discontinued due to investigator-determined treatment failure or lack of efficacy.
- Three BARACLUDE-treated patients and four adefovir-treated patients met the treatment response criteria at 52 weeks and entered a 24- or 48-week off-treatment follow-up monitoring phase.
- Two BARACLUDE-treated patients and one adefovir-treated patient were lost to follow-up, one BARACLUDE-treated patient was non-compliant, two adefovir-treated patients withdrew consent, one adefovir-treated patient became pregnant, and one adefovir-randomized patient was treated with BARACLUDE.

Week 12 (primary endpoint)

- BARACLUDE-treated patients achieved a mean change in viral load of $-6.23 \log(10)$ copies/mL from baseline, compared to adefovir-treated patients who achieved a mean change of $-4.42 \log(10)$ copies/mL (p < 0.0001).
- 12 percent of BARACLUDE-treated patients and 9 percent of adefovir-treated patients had undetectable viral load (HBV DNA <300 copies/mL).

Additional Cumulative Safety Results of the E.A.R.L.Y. Study at 96 Weeks

- 83 percent of patients in the BARACLUDE arm (n=30) and 82 percent of patients in the

adefovir arm (n=27) experienced any adverse event.

- Eight percent of patients receiving BARACLUDE (n=3) and 15 percent of patients receiving adefovir (n=5) experienced any Grade 3-4 adverse event.
- Three percent of patients receiving BARACLUDE (n=1) and 12 percent of patients receiving adefovir (n=5) experienced a serious adverse event.
- No deaths were observed in either treatment group.
- No patients in the BARACLUDE arm and one patient in the adefovir arm experienced an ALT flare (defined as ALT greater than two times baseline and greater than 10 times the upper limit of normal).

About the Study

The E.A.R.L.Y. study (ETV-079) is a randomized, open-label, comparative viral kinetics study of antiviral-naïve chronic HBeAg-positive patients evaluating antiviral activity as measured by mean reduction in viral load, or levels of hepatitis B virus (HBV DNA) in the blood. HBeAg or e-antigen, is a viral protein associated with hepatitis B infections, and is found in the blood only when there is virus present.

The primary endpoint for the study was mean reduction in HBV DNA levels at week 12. The secondary endpoints included the mean change in viral load from baseline through week 96, the proportion of patients in each treatment group who achieved ALT normalization, HBeAg loss and HBe seroconversion, and safety.

Sixty-nine patients were randomized in the study and of these, 65 completed the first 12 weeks. Patients in this study received either 0.5 mg of BARACLUDE(R) (entecavir) once daily (n=33) or 10 mg of adefovir once daily (n=32) for a minimum of 52 weeks. Patients in the BARACLUDE treatment group had a mean baseline viral load of 10.26 log(10) copies/mL. Patients in the adefovir treatment group had a mean baseline viral load of 9.88 log(10) copies/mL.

According to study protocol, patients who achieved a treatment response at 52 weeks discontinued treatment and entered a follow-up monitoring phase. Three BARACLUDE-treated patients and four adefovir-treated patients met this criterion and entered the follow-up monitoring phase lasting up to 48 weeks. Patients who did not achieve a treatment response at 52 weeks continued on study to 96 weeks. Treatment response in this study is defined as HBeAg seroconversion and viral load less than 10^4 copies/mL for 24 weeks, with undetectable viral load at the end of the 24-week period.

May 1st, 2007

Increased Knowledge and Awareness Top Priorities During Hepatitis Awareness Month

<http://www.marketwire.com>

VANCOUVER, WA--(Marketwire - May 1, 2008) - As Hepatitis Awareness Month kicks off May 1st, long-time hepatitis C patient advocate Lorren Sandt has one wish: that all people in the Pacific Northwest with chronic viral hepatitis have the information they need to be properly diagnosed. The Caring Ambassadors Hepatitis C Program (CAP Hepatitis C) is working in collaboration with other community-based organizations, nonprofit groups, and state and local

health departments to make that goal a reality.

More than 200,000 people living in Washington and Oregon are living with chronic viral hepatitis while thousands of new infections occur each year. "Everyone in America is aware of HIV. Unfortunately, very few know about hepatitis B and C despite the fact that they are much more prevalent than HIV throughout the U.S.," said Lorren Sandt, CAP Hepatitis C Program Director. "It is critical that we raise awareness now to contain the spread of this potentially life-threatening illness, and to help those already infected minimize the personal health consequences."

Governors Ted Kulongoski and Chris Gregoire have issued state proclamations in observance of Viral Hepatitis Awareness Month. The Governors realize the serious public health threat posed by chronic viral hepatitis to Oregonians and Washingtonians. They have leant their political and personal voices to the cause of raising awareness of the personal and community effects of chronic viral hepatitis. With at least 1 in 50 people in the Pacific Northwest infected with the hepatitis B or the hepatitis C virus, someone you know is living with this potentially life-threatening disease.

During Viral Hepatitis Awareness Month, CAP Hepatitis C, other community-based organizations, and some public health departments will be providing hepatitis C screenings free-of-charge to those who may have been exposed to the hepatitis C virus. Testing will be conducted at various locations throughout Oregon and Washington. Some locations will provide free vaccinations for hepatitis A and B. Visit www.HepCChallenge.org to find a screening location near you or call 360-816-4186.

About Chronic Viral Hepatitis

Hepatitis C is the most common chronic, blood-borne viral infection in the United States. An estimated 5 million Americans are infected with the hepatitis C virus (HCV), and 1.25 million have chronic hepatitis B. Hepatitis B is a vaccine-preventable disease. However, there is no vaccine available to prevent chronic hepatitis C. Chronic hepatitis B and C can lead to cirrhosis, liver failure, liver cancer, and death. Hepatitis C is the most common cause of chronic liver disease and adult liver transplantation in the United States.

About Caring Ambassadors Hepatitis C Program

The Caring Ambassadors Hepatitis C Program (CAP Hepatitis C) is devoted exclusively to meeting the needs of the hepatitis C community. CAP Hepatitis C is committed to improving the lives of people living with hepatitis C through information and awareness and public advocacy.

The Caring Ambassadors Program is a 501(c)(3) nonprofit public charity. Founded in 2001, the organization is headquartered in Vancouver, Washington, U.S.A.

For additional information about the Caring Ambassadors Hepatitis C Program and Hepatitis Awareness Month, contact Lorren Sandt at 360.816.4186 or Lorren@HepCChallenge.org.

Beckman Coulter Acquires Rights to Hepatitis C Virus

<http://www.earthtimes.org>

Enables Development of Molecular Quantitative Viral Load Assay

ORANGE COUNTY, Calif., April 30 /PRNewswire-FirstCall/ -- . Beckman Coulter, Inc. announced today that it has licensed certain rights to testing for the hepatitis C virus (HCV) from Siemens Healthcare Diagnostics. Under the agreement, Beckman Coulter can develop, manufacture and sell a quantitative viral load HCV blood test for use on the company's molecular diagnostic instrument, which is in development. As a result, Beckman Coulter expects to take a charge of \$12 million in the second quarter of 2008.

HCV viral load testing is essential for managing patients affected by the hepatitis C virus and is used to monitor therapy for the duration of the infection. An estimated 180 million people are chronically infected with the hepatitis virus and an additional 3 to 4 million people are newly infected each year. A hepatitis C infection can cause acute hepatitis and chronic liver disease including cirrhosis and liver cancer. Two thirds of all liver transplants in developed countries are the result of these diseases.

Scott Garrett, chairman, president and CEO of Beckman Coulter, commented, "We are enthusiastic about the opportunity to meet our customers' growing needs for HCV testing. Our access to this intellectual property will expand the served market for our 'sample-to-result' molecular diagnostics system, expected to launch in 2010."

"We are pleased to collaborate with Beckman Coulter to broaden the availability of this important test," said Dave Okrongly, senior vice president, molecular diagnostics, Siemens Healthcare Diagnostics Division. "This agreement reaffirms Siemens' commitment to enable physicians worldwide to improve the health care they offer patients."

Garrett added, "Routine molecular testing is the fastest growing segment in clinical diagnostics and represents an important part of our growth strategy. The addition of HCV will enhance our infectious disease test menu while furthering our dedication to improving patient health and reducing the cost of care."

About Beckman Coulter

Beckman Coulter, Inc., based in Orange County, California, develops, manufactures and markets products that simplify, automate and innovate complex biomedical tests. More than 200,000 Beckman Coulter systems operate in laboratories around the world, supplying critical information for improving patient health and reducing the cost of care. Recurring revenue, consisting of supplies, test kits, service and operating-type lease payments, represents approximately 78 percent of the company's 2007 annual revenue of \$2.76 billion.

For more information, visit <http://www.beckmancoulter.com/> .

Vertex Hep C Drug Still Leads Schering

<http://www.thestreet.com>

Adam Feuerstein

Competing hepatitis C drugs from Vertex Pharmaceuticals (VRTX - Cramer's Take - Stockpickr) and Schering-Plough (SGP - Cramer's Take - Stockpickr) went "Mano-a-Mano in Milano" this

weekend at a European liver disease meeting, and it was really no contest.

Victory Vertex.

Credit Sanford Bernstein biotech analyst Geoffrey Porges for the catchy "mano" line. The subhead of his Sunday night research note wasn't as cheeky, but should resonate just as much with investors Monday:

"Schering-Plough's Boceprevir Still Behind, Still Inferior to Telaprevir."

Telaprevir is Vertex's hepatitis C drug, which had a pretty good weekend at the European Association for the Study of Liver Disease annual meeting in Milan, Italy. On Thursday, telaprevir proved very capable of reducing the viral load of hepatitis C patients who had failed prior treatments. Then in a highly anticipated presentation Saturday, Schering-Plough's boceprevir couldn't match the "cure rate" standard for newly diagnosed hep C patients set earlier by Vertex's telaprevir.

Neither drug is approved yet, of course, and there isn't any real head-to-head data, so don't put any conclusions in ink just yet. With that said, however, the emerging story line from this weekend's meeting is that telaprevir and boceprevir are still No. 1 and No. 2 respectively, but the gap between the two drugs has widened.

Vertex shares closed Friday at \$25.72, while Schering-Plough closed at \$18.64.

In a phase II study of treatment-naïve hepatitis C patients, Schering's boceprevir achieved a sustained virologic response, or cure rate, after 12 weeks of 57% and 55% in two arms of a multi-arm phase II study that's still underway. Another 12 weeks of observation (for a full 24 weeks) will be required to determine the final cure rate for these patients.

But already, boceprevir has no hope of catching up to telaprevir, which posted final cure rates about 10% higher in its two phase II studies. Those data were presented at a U.S. liver disease meeting last November.

Rates of patient discontinuation and relapse were also relatively high in the boceprevir study presented Saturday, which don't appear to give the drug any discernible edge over the Vertex's telaprevir.

This study is ongoing so there is a lot of data not yet presented, including patients dosed with boceprevir for a longer period and a comparator arm of patients not given boceprevir.

Schering-Plough does plan on moving boceprevir into phase III studies, but with the phase II study still not completed, the company is at least one year behind Vertex, which has already begun its phase III telaprevir studies.

Hepatitis C drug development seems to take twists and turns on a weekly basis, so it's never safe to count any drug in or out. And boceprevir isn't the only competition facing telaprevir. There are promising drugs -- albeit in much earlier stages of development -- from Intermune (ITMN - Cramer's Take - Stockpickr), Johnson and Johnson (JNJ - Cramer's Take - Stockpickr), Merck

(MRK - Cramer's Take - Stockpickr) and Boehringer Ingelheim, among others.

With that said, Vertex and its shareholders have to feel good about telaprevir right now.

Bernstein's Porges, by the way, has an outperform rating and a \$45 price target on Vertex.

Hepatitis E breaks out on cruise ship

<http://www.upi.com>

LONDON, May 1 (UPI) -- Seven British people on the P&O cruise ship Aurora caught the hepatitis E virus while on a 12-week international cruise, officials said.

The vacationers, aged roughly between 50 and 80, are suspected of contracting hepatitis while the ship was stopped in a tropical region, the Daily Telegraph reported Thursday.

The cruise toured locations such as Madeira, Barbados, Venezuela, Bonaire in the Dutch Antilles, the Panama Canal and Acapulco in Mexico.

Infected travelers reportedly exhibited symptoms including jaundice, discomfort and diarrhea.

The virus, typically transmitted through water or food, can result in swelling of the liver. Symptoms may not appear for weeks after infection occurs.

The Health Protection Agency has begun an investigation into what started the outbreak, the report said.

It is reported that at least 1,100 people have been advised to have their blood tested for the illness.

Some have speculated the Aurora is cursed, partly because 600 people aboard it fell ill with the Norovirus in 2003, the report said.

Study: 1 in 50 NYC adults has Hep. C

<http://abclocal.go.com>

NEW YORK (WABC) -- At least one in 50 New York City adults is infected with hepatitis C, according to new findings from the Health Department.

But because many are unaware of their infection, they may miss out on the steps needed to protect themselves and prevent transmission.

Data from the city's Health and Nutrition Examination Survey show that 2 percent of New York City adults - about 130,000 people - are infected with the virus. The actual number is higher, because hepatitis C is especially prevalent among the homeless and the incarcerated - two groups not covered by this survey. National survey data yielded similar findings for the country as a whole.

What is Hepatitis C?

Hepatitis C is a blood-borne viral infection that damages the liver. Many people contracted it through blood transfusions before the blood supply was protected in 1992. It is also common among people who have used needles to inject street drugs. Hepatitis C can spread sexually or pass from mother to child at birth, but both are rare occurrences.

Some people can live with hepatitis C without ever suffering symptoms, but 15 percent of infected people develop cirrhosis - a scarring of the liver that can lead to cancer - and 4 percent of infections are fatal. The infection can progress silently for 10, 20 or 30 years, even when it is destroying the liver. Most people with hepatitis C are now in their 50s. Many are just now discovering that they were infected during the 1970s and 80s, through blood transfusions or shared needles.

Who Should Get Tested?

Hepatitis C spreads only through blood, not through food or casual contact. The people who most need to be tested are those who have:

- Ever injected street drugs, even just once or a long time ago
- Had a blood transfusion, received blood products, or had an organ transplant before July 1992
- Ever been on kidney dialysis
- Had unprotected sex with many partners, or with a partner who had Hepatitis C or injected drugs
- Received tattoos from someone other than a licensed professional
- Tested positive for HIV
- Been born in a country with a high Hepatitis C rate, such as Egypt or the Soviet Union

"Hepatitis C can be a very serious infection, causing liver disease and death," said Dr. Sharon Balter, Medical Epidemiologist in the Health Department's Bureau of Communicable Disease. "The infection may not cause symptoms for decades, even though it is damaging the liver. If you have ever injected drugs - even once, decades ago - you should get tested. And if you received blood more than 15 years ago, you should get tested, too. If you are positive, treatment is available. There are things you can do to control the virus and stay healthy."

How to Prevent Hepatitis C

There is no vaccine against hepatitis C. Here is how you can protect yourself:

- Don't inject street drugs. If you do, use a new needle and injecting equipment every time. For more information, go here.
- Practice safer sex by using latex condoms. Avoid sexual acts that can tear body tissues and draw blood.
- If you get tattoos, get them only from a licensed professional
- Don't share toothbrushes, razors, or other personal care items that may have blood on them. Living with Hepatitis C: Take Care of Yourself
- Most people who contract hepatitis C virus will remain infected for the rest of their lives. But tests can determine whether the virus is active in your body, and medication can suppress it about 50 percent of those who take it. If you are infected, taking care of your liver is critical.

Here are of the most important ways to protect yourself:

- Do not drink alcohol. Drinking can make your liver disease much worse.
- Get the Right Medical Care. See a doctor who knows about Hepatitis C - even if you don't feel sick. People with chronic Hepatitis C need regular check-ups.
- Get vaccinated against hepatitis A and B. These are different infections, but they can accelerate the harm that Hepatitis C causes.
- Eat well, rest, and exercise to help your body stay healthy.
- Talk about your feelings. Finding out that you have Hepatitis C can be overwhelming. You may feel scared, sad, angry, confused and upset. These feelings are normal and can get better with time.

Health Department Efforts to Reduce Hepatitis C

The Health Department works with community partners to increase awareness, promote screening, and improve care for Hepatitis C. Efforts include:

- Offering free Hepatitis C testing at STD clinics throughout the city. Over 1,000 people were tested in 2007 at STD clinics and partner agencies. For testing locations, call 311.
- Convening quarterly meetings of the Brooklyn and Bronx Hepatitis C Taskforce. A new Task Force in Queens will meet for the first time this month. These groups bring together community organizations and advocates working together to raise awareness and increase screening and care.
- Providing free training and educational materials to more than 500 health care providers each year.
- Promoting safe needle use and reducing transmission by supporting 13 needle exchanges in the city. Clean needles can prevent Hepatitis C and HIV without causing any increase in injection drug use.

Las Vegas Hepatitis C Doc Blocked From Medicine

<http://www.injuryboard.com>

Posted by Jane Akre

Dr. Dipak Desai, linked to a hepatitis C outbreak in Las Vegas, had his medical license blocked by a judge's temporary restraining order issued Tuesday.

The order was requested by state Attorney General Catherine Cortez Masto pending the outcome of a Board of Medical Examiners 10-count complaint against Dr. Desai.

Dr. Desai had voluntarily surrendered his license following the hepatitis C outbreak at one of his clinics, the Endoscopy Center of Southern Nevada, but that still allowed him to practice medicine outside of Nevada.

“Imminent and irreparable harm will result” if the order isn’t immediately issued, District Judge David Wall told the Las Vegas Review Journal.

The Las Vegas Sun is reporting today that Dr. Desai tried to ship two luxury vehicles to Dubai. The general manager of the car dealership told the paper that Desai brought a broker from Dubai to his dealership and tried to pay off two black Mercedes vehicles, valued at about \$250,000, but

the dealer denied the request.

There has been speculation that the native of India might flee the country. His wife, Dr. Kusum Desai, a pulmonary specialist, has quit her practice which was not linked to her husband's clinics.

Dr. Eladio Carrera, who was co-owner with Desai of another endoscopy center on Shadow Lane, is also facing a restraining order that prevents him from practicing medicine.

The doctors are accused of putting patients' health in jeopardy, putting the medical profession in disrepute, putting financial gain above the patient and failing to use "reasonable care, skill or knowledge ordinarily used under similar circumstances."

The complaint alleges that Doctors Desai and Carrera directly worked on three patients who were infected with hepatitis C.

The medical board, Las Vegas Police, FBI, State Attorney's office and Clark County district attorney's office are all investigating the Endoscopy Center and possible insurance fraud.

40,000 former patients are undergoing hepatitis C, B and HIV testing after it was revealed in February that eight patients have contracted hepatitis C from a contaminated re-used syringe at three centers owned by Dr. Desai.

Under Desai's direction workers also allegedly reused needles and vials. There is no cure for hepatitis C, a blood borne disease that causes inflammation of the liver. It can lead to cirrhosis, cancer and death.

May 8th a Las Vegas court hearing will determine whether the temporary order should become a preliminary injunction against Dr. Desai. So far he has paid the city \$500,000 in fines.

The first medical negligence lawsuit has been filed in District Court by a former patient of the Endoscopy Center. Charles Anthony Rader, 53, who along with his wife is being tested for hepatitis and HIV.

Rader's case was among the first in a class action negligence lawsuit filed by White, Meany and Wetherall of Las Vegas, a member of Injuryboard. #

Anti-fibrotic Mechanism Of A Chinese Medicinal Herb May Inspire Drug Development

<http://www.sciencedaily.com>

ScienceDaily (May 1, 2008) — A team led by Dr. Xue-Hai Tan from the Beijing Genomics Institute has determined that the antifibrotic function of Chinese herbal extract Cpd 861 is mediated by both downregulating the synthesis of collagens and upregulating the degradation of collagens. This effect is evidently different from that of Western antifibrogenic drugs and could allow for the development of effective antifibrogenic drugs from Chinese medicinal herbs.

In human hepatic stellate cells, the key cells involved in both the synthesis and degradation of

matrix proteins (mainly collagens) in the liver, the plant extract Cpd 861 can regulate the expression levels of collagen synthesis and degradation-related genes, thus demonstrating an antifibrotic effect.

Hepatic fibrosis, which can lead to portal hypertension or cirrhosis, is a wound-healing response to chronic liver injuries due to a variety of insults. The altered balance between the synthesis and degradation of matrix proteins (mainly collagens) is the major pathogenic feature in the hepatic fibrosis process. Although remarkable progress has been made recently in understanding the mechanisms of hepatic fibrosis and while numerous agents have been studied, very few effective antifibrogenic drugs have been approved for use in humans.

Previous research has showed that Cpd 861, which was formulated by one the authors (Dr. Bao-En Wang) in accordance with traditional Chinese medical theory, can significantly improve the clinical manifestations and biochemical parameters of patients with hepatic fibrosis. Their recent work found that the antifibrotic function of Cpd 861 is mediated not only by inhibiting collagen synthesis (by downregulating collagen type III gene expression) but also by enhancing the degradation of collagens (by increasing the expression of matrix metalloproteinase-1, which is an enzyme that degrades collagens). These effects are different from those of Western antifibrogenic drugs (such as interferon- gamma).

The authors explain that the herbs used to prepare Cpd 861 have been used for thousands of years in Traditional Chinese Medicine, and the results of this research could allow for the development of effective antifibrogenic drugs from Chinese medicinal herbs.

Using human hepatic stellate cells and a real-time quantitative PCR method, this research was performed by physicians from the Beijing Genomics Institute, the Liver Research Center of the Beijing Friendship Hospital, and the Institute of Medicinal Plant Development of the Chinese Academy of Medical Sciences, China.

Further research should be done to explain the mechanism for Cpd 861's regulation of collagen-related gene expression and to identify the active antifibrotic ingredient in Cpd 861.

Reference: Wang L, Wang BE, Wang J, Xiao PG, Tan XH. Herbal compound 861 regulates the mRNA expression of collagen synthesis and degradation related genes in human hepatic stellate cells. *World J Gastroenterol* 2008; 14(10): 1790-1794 <http://www.wjgnet.com/1007-9327/14/1790.asp>

Adapted from materials provided by World Journal of Gastroenterology, via EurekAlert!, a service of AAAS.

May 2nd, 2007

Medical marijuana user dies for lack of liver transplant

<http://seattletimes.nwsourc.com>

By The Associated Press

Tim Garon lies in his hospital bed as his girlfriend, Leisa Bueno, leans over to give him a kiss while they wait to hear if he will be put on a transplant list to receive a new liver Thursday, April

24, 2008, in Seattle. Garon died Thursday.

Marijuana Liberation Day

Advocates of liberalizing marijuana laws plan to march Saturday in Seattle from Volunteer Park on Capitol Hill to Westlake Park downtown. The march begins about noon and speeches at Westlake Park are scheduled from 2 to 3:30 p.m. The event coincides with other similar events in as many as 200 other cities nationwide.

A musician who was denied a liver transplant because he used marijuana with medical approval under Washington state law to ease the symptoms of advanced hepatitis C died Thursday.

The death of Timothy Garon, 56, at Bailey-Boushay House, an intensive care nursing center was confirmed to The Associated Press by his lawyer, Douglas Hiatt, and Alisha Mark, a spokeswoman for Virginia Mason Medical Center, which operates Bailey-Boushay.

Dr. Brad Roter, the physician who authorized Garon to smoke pot to alleviate for nausea and abdominal pain and to stimulate his appetite, said he did not know it would be such a hurdle if Garon were to need a transplant.

The case has highlighted a new ethical consideration for those allocating organs for transplant, especially in the dozen states that have medical marijuana laws: When dying patients need a transplant, should it be held against them if they've used pot with a doctor's blessing?

Garon died a week after his doctor told him a University of Washington Medical Center committee had again denied him a spot on the liver transplant list.

"He said I'm going to die with such conviction," Garon told an AP reporter at the time. "I'm not angry, I'm not mad, I'm just confused."

Garon believes he contracted hepatitis C by sharing needles with "speed freaks" as a teenager. In recent years, he said, pot has been the only drug he's used. In December, he was arrested for growing marijuana.

He had been in the hospice for two months and previously was rejected for a transplant at Harborview Medical Center.

Harborview said he would be considered if he avoided pot for six months and the university hospital offered to reconsider if he enrolled in a 60-day drug treatment program, but doctors said his liver disease was too advanced for him to last that long. The university hospital committee agreed to reconsider anyway, then denied him again.

P-HOP Event To Provide Free Hepatitis C Testing To The Community - P-HOP Recognizes May As Hepatitis Awareness Month

<http://www.medicalnewstoday.com>

Philadelphia Hepatitis Outreach Project (P-HOP), in partnership with the New Pathways for Women Project, is conducting a community health fair on May 31, 2008 from 10 a.m. to 3 p.m.

at the New Pathways for Women Project office at 2539 Germantown Avenue, Philadelphia.

In recognition of May as Hepatitis Awareness Month, P-HOP will offer free Hepatitis C Virus (HCV) screening, HIV counseling and rapid testing, as well as information about an array of other health and social services available to the community. Refreshments and entertainment will be provided.

P-HOP, a program of Philadelphia Health Management Corporation (PHMC), provides community-based viral hepatitis education, screening and outreach services. The New Pathways for Women Project, a collaboration between PHMC and the Black Women's Health Alliance (BWAHA), provides community outreach services to substance-involved African American women who are at high risk for HIV infection.

The majority of P-HOP's services are provided in city-funded substance abuse treatment facilities, given the very high rate of HCV infection among individuals with histories of drug use. Data from the Center for Disease Control and Prevention (CDC) estimated that 60% of those infected with HCV contracted the virus through injection drug use. "Currently, HCV positive rates for consumers of city-funded methadone clinics approach 85%," explains program coordinator, Teresa Lamore. "This program helps treatment providers integrate client-centered hepatitis support services into their routine of HIV early intervention and substance abuse recovery operations."

HCV is spread through blood to blood contact and causes infection of the liver. Lamore said, "According to the CDC, it is estimated that 4.1 million Americans have been infected with HCV, and that each year an additional 19,000 people become infected."

There is currently no vaccine to combat HCV; therefore prevention is crucial. P-HOP has found that free screenings, where issues such as HCV prevention and treatment can be openly discussed, best educate individuals most at risk. Community health fairs are specifically designed to support treatment, reduce disease transmission through education, ensure clients are linked to available insurance, and provide information on medical and community support. Lamore adds, "Most importantly, the role of an HCV Outreach Support Specialist is to provide one-on-one personal encouragement and advocacy for consumers and to work with them to counter the fear, stigma, and misinformation associated with HCV."

About P-HOP

Philadelphia Hepatitis Outreach Project (P-HOP) conducts basic viral hepatitis education presentations and screening events for Hepatitis C Virus (HCV) consumers, as well as specialized seminars on treatment issues and challenges for those consumers living with HCV. The primary goals of P-HOP are to increase the number of individuals who know their HCV status through onsite HCV screening; the promotion of positive and healthy outcomes of individuals living with HCV through education, advocacy, outreach, and linkage to care; and to reduce the transmission of viral hepatitis to others.

About New Pathways for Women Project

The New Pathways for Women Project, a collaboration between PHMC and the Black Women's Health Alliance (BWAHA), provides community outreach services to substance-involved African American women who are at high risk for HIV infection. Through enrollment in the program, the

women receive individual pre-treatment counseling, case management, support services, on-site rapid HIV testing, and, as needed, referral and accompaniment to confirmatory HIV testing, HIV primary care and case management services, substance abuse treatment, and other support services.

About PHMC

The Philadelphia Health Management Corporation (PHMC) is a nonprofit public health institute that builds healthier communities through partnerships with government, foundations, business and other community-based organizations. It fulfills its mission to improve the health of the community by providing outreach, health promotion, education, research, planning, technical assistance, and direct services. PHMC has served the Greater Philadelphia region since 1972.