

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Believe in the Cure Bicycling Tour Comes to Philly

<http://www.kyw1060.com>

Beginning on Monday, 17-year-old John Ellis will embark on a 1,100 mile bike ride from his hometown of Pensacola, Florida to Philadelphia to benefit the Hepatitis B Foundation which is headquartered in Doylestown.

Ellis himself was diagnosed with Hepatitis B back in 2006 and he says the Believe in the Cure Cycling Tour has been about a year in the making. He and his friend Jamaal are set to travel some 1,100 miles. Arriving in Philadelphia on June 23rd, Ellis talks about what he hopes people take from his journey:

"I guess all I can really hope for is they can see me obviously not letting Hepatitis B get me down and hopefully it will just draw people's attention to it. Hepatitis B is still prevalent and it's still something we need to work towards treating better."

Hepatitis B is the world's most common serious liver infection. It is caused by the hepatitis B virus that attacks liver cells and can lead to cirrhosis, liver failure, and liver cancer.

For more information on the Believe in the Cure Cycling Tour, go to <http://hepb.org/>.

Officials gripe about health probe

<http://www.sfgate.com/>

By Brendan Riley, Associated Press Writer

Gov. Jim Gibbons and several legislators say three temporary state Board of Medical Examiners members, named in early April to help speed an investigation into a southern Nevada hepatitis outbreak, still haven't been contacted by the board.

Gibbons, joined by state Sens. Randolph Townsend, R-Reno, Joe Heck, R-Henderson, and Steven Horsford, D-North Las Vegas, and Assemblywoman Sheila Leslie, D-Reno, also said the board hasn't held a hearing to describe its plan for investigating doctors involved in the outbreak.

"At this point, we see no alternative but to demand an immediate and detailed report of all actions the board has taken to date to address the role any Nevada physicians may have played in the outbreak," the governor and lawmakers said in a letter to Dr. Javid Anwar, the board president.

The letter also states that Tony Clark, executive director of the medical panel, "has demonstrated an unwillingness to vigorously handle the matter."

Anwar didn't respond immediately to a call Friday seeking comment on the letter. Clark said the letter was being reviewed by the board's legal counsel, and a response from the board wasn't likely until Monday.

Gibbons announced April 2 that Drs. Ronald Kline, Beverly Neyland and Robert Wiencek, all

from southern Nevada, would temporarily replace Anwar and two other doctors with ties to Dr. Dipak Desai, owner of a Las Vegas clinic where flawed procedures led to the hepatitis outbreak.

Besides Anwar, S. Daniel McBride and Sohail Anjum also were replaced. The letter from Gibbons and the legislators said Anwar is still board president and responsible for quick action by the panel.

The Centers for Disease Control and Prevention said in a recent report that the staff at Desai's Endoscopy Center of Southern Nevada likely caused the transmission of the bloodborne pathogen by "routinely mishandling injection equipment and single-use medication vials."

The CDC's report bolsters earlier conclusions by Clark County and state health officials about the outbreak that led to the biggest public health notification operation in U.S. history. Officials have linked 84 cases of the potentially deadly liver disease to the clinic and have notified 50,000 patients that they may be at risk.

Hepatitis C results in the swelling of the liver and can cause stomach pain, fatigue and jaundice. It may eventually result in liver failure. Even when no symptoms occur, the virus can slowly damage the liver.

June 2, 2008

Anadys Pharmaceuticals Initiates Phase I Clinical Trial of ANA598

<http://www.examiner.com>

SAN DIEGO, June 2 /PRNewswire-FirstCall/ -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) announced today the initiation of dosing in a Phase I clinical trial of **ANA598**, an investigational oral non-nucleoside polymerase inhibitor for the treatment of chronic hepatitis C virus (HCV) infection. The objectives of this trial are to assess safety, tolerability, and pharmacokinetics following ascending single oral doses of ANA598 in healthy volunteers. Approximately 40 healthy subjects will participate in the study, which is being conducted in the United States. Following successful completion of the healthy volunteer study, Anadys plans to begin a Phase Ib study of ANA598 in HCV-infected patients in the third quarter of 2008.

"Based on its very favorable preclinical profile, including potency, pharmacokinetics, and tolerability, we believe ANA598 has the potential to become an important component of future combination therapy for patients with HCV infection," said James Freddo, M.D., Anadys' Chief Medical Officer. "We are excited about initiating this clinical program and look forward to future trials of ANA598 in HCV patients, first as a single agent and then in subsequent combination studies. We expect the full benefit of direct antivirals to be demonstrated when studied as components of novel combination regimens incorporating multiple anti-HCV agents."

Steve Worland, Ph.D., Anadys' President and CEO commented, "This is a significant milestone for Anadys. ANA598 is the second internally discovered compound that we've moved into clinical studies this year. With the commencement of dosing in a Phase I clinical trial for ANA773 in cancer patients in February and this study of ANA598 underway, Anadys is now focused on achieving important clinical milestones in both programs."

About ANA598

ANA598 is a highly potent and selective inhibitor of HCV genotypes 1a and 1b NS5b RNA polymerases (IC₅₀ < 1 nM) and of HCV replication in cell culture (EC₅₀ values for genotypes 1b and 1a replicons are 3 and 50 nM, respectively). ANA598 has been well-tolerated in all preclinical studies, including 28-day GLP toxicology studies, and was selected as a development candidate in June 2007.

Clinical Need and Market Opportunity in HCV Infection

Chronic hepatitis C virus (HCV) infection is a serious public health concern affecting approximately 2.7 million people in the United States and approximately 170 million people worldwide. HCV causes inflammation of the liver, which may lead to fibrosis and cirrhosis, liver cancer, and ultimately, liver failure. Cirrhosis of the liver resulting from chronic HCV infection is the leading indication for liver transplantation in the U.S. Due to the asymptomatic nature of HCV infection, it often goes undetected for up to 20 years following initial infection. Each year, 8,000 to 10,000 people in the U.S. die from complications of HCV.

The current standard of care is a combination of pegylated interferon and ribavirin. Inadequate response rates, in particular for patients infected with genotype 1 HCV, along with significant side effects of approved therapy, support the medical need for improved treatment options. It is estimated that fewer than 5% of people with chronic HCV infection living in the U.S. are under treatment today. The majority of infected individuals are unaware of their infection status and the large majority of individuals who know their status do not currently receive drug therapy. There is also a growing number of individuals who have failed interferon-based regimens who may be successfully treated with combinations of two or more direct antivirals. It is expected that the next generation of therapies for treatment of HCV will include small molecules, such as ANA598, that act directly upon specific viral enzymes to inhibit viral replication. These direct antivirals are expected to improve overall therapy by increasing cure rates and improving tolerability and convenience of treatment.

About Anadys

Anadys Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. The Company is developing ANA598, a non-nucleoside polymerase inhibitor for the treatment of chronic hepatitis C and ANA773, an oral TLR7 agonist prodrug for the treatment of cancer.

June 3, 2008

Immtech Announces Results From Hepatitis C Discovery Program

<http://biz.yahoo.com>

NEW YORK, June 3 /PRNewswire-FirstCall/ -- Immtech Pharmaceuticals, Inc. (Amex: IMM - News) announced today positive results against the hepatitis C virus (HCV) of a compound from its drug discovery portfolio. The prototype compound belongs to an expanding class of compounds that has previously demonstrated activity against a related surrogate virus, bovine viral diarrhea virus (BVDV). The compound was found to have significant activity against HCV under assay conditions designed to demonstrate inhibition of the virus entry process, using a newly available in vitro cell culture system that employs infectious and replicating virus.

Norman Abood, Ph.D., Sr. Vice President, Discovery Programs, stated, "We aim to develop a

compound with a novel mechanism of action that is complementary to the currently recognized treatments of HCV. It appears that Immtech's class of compounds inhibits an early, non-replicative step in the virus life cycle, based upon our earlier work in BVDV. The majority of the industry's efforts have focused on programs to identify drug candidates, such as protease and polymerase inhibitors, which inhibit HCV virus replication. Our latest findings provide an approach that will allow us to potentially identify a drug candidate with a new and complementary mechanism of action."

As of 2005 there were more than 11 million people living with hepatitis C in major markets around the world, and the sale of drugs to treat the disease, including treatments that are prescribed after a first course of treatment fails, was \$3 billion. The HCV drug market is expected to expand to \$9 billion in 2012 and to more than \$10 billion annually by 2014.

About Immtech Pharmaceuticals, Inc.

Immtech is a pharmaceutical company focused on the development and commercialization of new drugs to treat infectious diseases. Immtech has a well defined, expanding library of compounds targeting Hepatitis C, drug-resistant Gram-positive bacteria, fungal infections and other serious diseases. It is expanding its targeted markets by applying its proprietary pharmaceutical platform to treat a range of disorders. Immtech holds exclusive worldwide licenses to certain patents, patent applications and technology for products derived from its proprietary pharmaceutical platform. For additional information, please visit the Company's website at <http://www.immtechpharma.com>

Source: Immtech Pharmaceuticals, Inc.

Police expect lengthy investigation into Las Vegas clinic

<http://www.smdailyjournal.com>

The Associated Press

LAS VEGAS — Authorities investigating the Las Vegas clinic at the center of a large hepatitis C outbreak say the investigation has been slowed by clinic workers who have refused to talk.

"I'd be very surprised if we don't go into next year," Las Vegas police Capt. Al Salinas said of the investigation of the Endoscopy center of Southern Nevada. "It's going to be a long investigation."

Salinas is leading a group of detectives who are interviewing witnesses and reviewing patient files to build cases against those believed to be responsible for the transmission of the bloodborne pathogen.

Chief Deputy District Attorney Scott Mitchell said some clinic workers have given statements, but nurse anesthetists and doctors have been reluctant to cooperate with investigators.

"We could stand to have a few people do the right thing and not worry so much about self-preservation," Mitchell said. "The longer you wait, the less we'll need you and the less willing we'll be to offer some sort of deal to you."

Federal and local public health officials have blamed the outbreak on practices of reusing syringes and single-use medication vials. The outbreak led to the biggest public health notification operation in U.S. history. Officials have linked 84 cases of the potentially deadly liver disease to the clinic and have notified 50,000 patients that they may be at risk.

Hepatitis C results in the swelling of the liver and can cause stomach pain, fatigue and jaundice. It may eventually result in liver failure. Even when no symptoms occur, the virus can slowly damage the liver.

Mitchell said that criminal charges including medical neglect could be filed within three or four months if the investigation continues at its current pace.

“Some people are becoming less obvious targets, and some people are becoming more obvious targets,” Mitchell said.

Mitchell said the charges would focus on the confirmed infections to keep the case from getting too big.

Salinas said the investigation is a priority for the department but won't be rushed.

“People want closure. They want resolution, but we have to cross our T's and dot our I's,” Salinas said.

“Maybe it's going to take the first few prosecutions before the rest realize this is serious,” he said.

Information from: Las Vegas Review-Journal, <http://www.lvrj.com>

June 4, 2008

Twelve-Week Protease-Based Triple Therapy Results in High HCV Cure Rates

www.medscape.com

Martha Kerr

May 28, 2008 (San Diego, California) – Hepatitis C viral (HCV) response to antiviral therapy "can be dramatically improved" with the addition of the investigational protease inhibitor telaprevir (VX-950, Vertex Pharmaceuticals, Inc.) to standard treatment with ribavirin plus pegylated interferon-alpha-2a (peg-INF), investigators in the landmark PROVE1 and PROVE2 trials reported here during Digestive Disease Week 2008.

"Ribavirin plus [peg-INF] is the backbone of [HCV] treatment. That's why any new drugs are tested against this background," lead investigator Gregory T. Everson, MD, professor of medicine and director of hepatology at the University of Colorado Health Sciences Center, in Aurora, noted in an interview with Medscape Gastroenterology after announcing the results of the PROVE1 study.

PROVE1 and PROVE2 were designed to evaluate whether rapid HCV suppression translates

into a sustained viral response (SVR) and whether triple therapy with telaprevir, ribavirin, and peg- $\text{INF-}\alpha\text{-2a}$ can lead to a shorter overall treatment duration.

PROVE1 was a 4-group phase 2b trial of 250 treatment-naïve patients with HCV genotype 1 conducted at 37 centers in the United States. Patients randomized to the control group received the standard of care (peg- INF 180 μg weekly and ribavirin 1000 to 2000 mg daily). Patients randomized to the treatment groups received standard of care plus 12, 24, or 48 weeks of telaprevir 750 mg every 8 hours.

The primary end point was an undetectable SVR 24 weeks after the end of treatment. Undetectable SVR was defined as less than 10 IU/mL HCV RNA copies, measured using the Roche TaqMan assay.

PROVE2 was a 28-center phase 2b European trial of 323 treatment-naïve genotype 1 HCV patients who were randomized to 1 of 4 groups: standard of care (peg- INF 180 μg weekly and ribavirin 1000 to 1200 mg daily) plus placebo telaprevir; standard of care plus 12 or 24 weeks of telaprevir 750 mg every 8 hours; and peg- INF 180 μg weekly plus telaprevir 750 mg every 8 hours. The primary objective was an undetectable SVR.

In PROVE1, Dr. Everson announced that the viral response to therapy at 4 weeks was greater with triple therapy (79%) than with standard treatment (11%). At week 12, viral response rates were 70% with triple therapy and 39% with dual therapy.

At 12 weeks, 91% of subjects on triple therapy and 43% of subjects on standard therapy had undetectable viral loads. At 48 weeks, SVR was 65% in patients on triple therapy and 45% in controls.

The relapse rate at 48 weeks was 2% in PROVE1 and 7% in PROVE2 (a combined relapse rate of 5%) in patients on the 24-week telaprevir-based regimen who had undetectable SVR at weeks 4 and 12.

The relapse rate for controls was 23% in PROVE1 24 weeks after the end of the 48-week standard-therapy regimen and 20% in PROVE2 at 12 weeks posttreatment.

"The take-home message is that patients may be able to get away with as little as 12 weeks of therapy using telaprevir with standard therapy," Dr. Everson told *Medscape Gastroenterology*. "The PROVE1 data pretty much convinced us that 24 weeks induces a sufficient and rapid viral response."

"Larger phase 3 trials will show whether or not shorter courses of treatment for a larger percentage of treatment-naïve genotype 1 HCV patients can be recommended," Dr. Everson said.

Triple therapy was "generally well tolerated," with some incidence of rash, gastrointestinal symptoms, and anemia; the adverse-event rate was 20% with and 11% without telaprevir. Hemoglobin levels dropped from 12 g/dL to 11 g/dL, which is statistically significant, "but we don't know if this is clinically significant," the PROVE1 investigator noted. "Hemoglobin levels rebounded after discontinuation of treatment, indicating bone marrow recovery."

"The bottom line is we can boost antiviral response about 50% with triple therapy.... [Response] is around 40% with standard therapy, [but] another 50% with triple therapy results in overall response rates of around 70%," Dr. Everson explained.

"This telaprevir study has been long-awaited," said John M. Vierling, MD, FACP, professor of medicine and surgery and chief of hepatology at Baylor College of Medicine in Houston, Texas, who was not involved in either of the studies, in an interview with Medscape Gastroenterology.

He pointed out that telaprevir is a protease inhibitor "very specifically targeted to HCV.... With such a specific target, it can rapidly mutate and develop resistance. That's why it has to be combined with ribavirin and peg-interferon.... With 'cocktail therapy,' no real resistance develops."

"We now have proof of principle," Dr. Vierling told Medscape Gastroenterology. "I hate to use the word cure, but we appear to have a cure rate of about 41% [in both PROVE1 and PROVE2].... The problem is that with a rapid sustained viral response, there is no acquired immunity..., [instead] we prevent a host response."

"Patients are currently treated for at least 48 weeks," Dr. Vierling said. "The ultimate goal is treatment with a protease inhibitor and a polymerase inhibitor, and to eliminate interferon or ribavirin, but polymerase inhibitor trials have had some hiccups."

Dr. Everson believes that "the ideal may be 12 weeks of triple therapy [followed by] 12 weeks of ribavirin plus peg-INF; then, antiviral treatment might be able to be stopped."

Dr. Everson's study was supported by a grant from Vertex Pharmaceuticals, Inc. Dr. Vierling describes himself as having "neutralized conflicts," serving as an advisor to "all the HCV pharmaceutical companies."

Digestive Disease Week (DDW) 2008: Abstracts 160 and 223. Presented May 18 and 19, 2008.

I tried to deny I had Hepatitis C. Now I'm glad I had treatment

<http://www.worcesternews.co.uk>

By James Connell

WHEN Phil noticed his skin was turning yellow he pushed it to the back of his mind.

It was the 1970s and, at the time, he was in the throes of alcohol and drug addiction.

He assumed the jaundice, which would come and go for periods of three or four weeks, was due to his lifestyle and forgot about it.

Even when, in 1989, a former partner rang and told him she had been diagnosed with Hepatitis C, Phil, who is now in his 50s, still took no action.

He said: "I thought, I'll deal with it when it starts affecting me' but when you are using very powerful painkillers, like heroin, you don't feel aches and pains.

"It wasn't until 10 years later in 1999 when I found myself in rehab I decided to get myself checked out."

The results were a mixed bag. Phil, who lives in Worcester but whose identity we have concealed, was clear of HIV and, although he had had Hepatitis B - probably the cause of his earlier jaundice - his body had already fought the virus off.

The bad news was he had contracted a form of Hepatitis C known as genotype one, the most difficult to treat.

It was no great surprise for Phil as Hep C, a blood-borne virus causing inflammation of the liver, is most commonly - but not exclusively - seen among users of intravenous drugs and, initially, he was not too concerned.

He said: "At the time I thought, let's look on the positive side, you've only got Hep C, you could be living with a death sentence like HIV'."

He was offered treatment but decided to concentrate on his rehab and recovery and it was only when, four years later he began to feel ill, that he changed his mind.

He said: "I went back into engineering and I was working and then getting home and I was knackered and all I wanted to do was have something to eat and lay on the settee in front of the TV.

"I tried to deny it by blaming it on my age but I got to the point when I couldn't deny it any longer - it was the Hep C."

Shockingly, Phil's doctor initially told him - wrongly - there was no treatment available but he insisted on being referred to a specialist.

He was seen by a consultant and clinical nurse specialist working in Worcestershire and underwent a biopsy which showed he did not have cirrhosis but his liver was damaged. If Phil had had genotype two or three, his odds of successful treatment would have been high but because he had type one, he only had a 50-50 chance of success.

Even so, he decided to go ahead with 48 weeks of treatment that included injecting his stomach or thigh once a week and taking tablets on a daily basis.

He said: "It was unnerving. It seemed quite surreal, I'd got syringes and swabs in the house again. It was a little bit strange."

After four years of being free from drink and drugs, he struggled with the idea of putting chemicals into his body but persevered and was eventually given the all-clear.

He said: "I'm grateful that I cleared it. It has enhanced my life.

"I've got more energy, more vitality, more lust for life."

However, he added: "I started treatment at the same time as a friend of mine and it didn't work for him. That's the 50-50 chance."

During his treatment, Phil lost his appetite, felt very tired and stopped work - although he stressed many others do carry on with their normal lives.

He now wants others to be screened and urged people not to feel anxious or ashamed, pointing out that addiction can make people do things - like sharing needles - that they would not normally consider.

He said: "You no longer have to have a biopsy, it's just a liver scan.

"The nurses are wonderful, caring people. They are very supportive. They are not there to judge you but to help you.

"If you believe you have Hep C then go along to your doctor and see.

"There is an answer to it and you can have treatment."

What Is Hepatitis C?

Hepatitis C is a blood-borne virus often associated with intravenous drug users but also affecting haemophiliacs and those who had blood transfusions prior to 1991, when blood screening was introduced. Although many sufferers can lead normal lives, up to 20 per cent go on to develop liver disease, need a transplant or suffer liver failure. 80 per cent of sufferers will need treatment.

Other forms of Hepatitis

Hepatitis A is a virus spread through contact with contaminated food or water and is often associated with holidays. You can be immunised against it and most people recover after a few weeks.

Hepatitis B is a virus transmitted through blood or bodily fluids, often via sexual transmission or intravenous drug use. You can be immunised against it but 96 per cent of people will recover without treatment.

Reduced Hepatitis C Viral Level Achieved with DNA Vaccine Delivered by Inovio Biomedical's Electroporation Delivery System in Phase I/II Clinical Study

<http://www.businesswire.com/>

SAN DIEGO--(BUSINESS WIRE)--Inovio Biomedical Corporation (AMEX:INO), a leader in enabling the development of DNA vaccines using electroporation-based DNA delivery, announced today that its partner, Tripep AB, reported preliminary results indicating a dramatic reduction in hepatitis C viral load in its ongoing phase I/II clinical study of its **ChronVac-C®** therapeutic DNA vaccine, which is delivered using Inovio's electroporation-based DNA delivery system. This result is from the first patient in the middle dose group to complete treatment against hepatitis C virus infection. Samples taken before, during and after treatment show that

the viral levels in blood successively decreased by more than 95% during treatment. Inovio's electroporation delivery technology is intended to enhance the potency of DNA vaccines against cancers and infectious diseases.

ChronVac-C® is a therapeutic vaccine given to individuals already infected with the hepatitis C virus with the aim to clear the infection by boosting the immune response against the virus. This clinical study is being conducted at the Infectious Disease Clinic and Center for Gastroenterology at the Karolinska University Hospital in Huddinge and Solna, respectively, in Sweden. The intended enrollment of 12 patients will be divided into three dose groups with increasing doses of ChronVac-C(R). Each patient receives four vaccinations one month apart. After the last vaccination, patients are followed for another six months. The study's main purpose is to assess safety. It is also testing whether the treatment boosts the immune response to HCV (immunogenicity) and its effect on virus replication in the liver. If the patient is completely virus-free six months after completing treatment, he/she will be considered cured.

In the lowest dose group, two patients who completed treatment developed a T-cell response to hepatitis C. The preliminary result from this first patient to complete treatment in the intermediate dose group is the first to indicate a significant reduction in viral load. There have been no severe adverse events.

“The benefit we would hope to see from a successful hepatitis C virus DNA vaccine would be a dramatic reduction in viral levels,” stated Avtar Dhillon, MD, Inovio's president and CEO. “We look forward to seeing the longer term results of this DNA vaccine and its potential to address this multi-billion dollar market.”

About Inovio Biomedical Corporation

Inovio Biomedical (AMEX:INO) is focused on developing multiple DNA-based immunotherapies and DNA vaccines. Inovio is a leader in developing human applications of electroporation using brief, controlled electrical pulses to increase cellular uptake of a useful biopharmaceutical. Human data has shown that Inovio's electroporation-based DNA delivery technology can significantly increase gene expression and immune responses from DNA vaccines. Immunotherapy partners include Merck, Wyeth, Vical, University of Southampton, Moffitt Cancer Center, the U.S. Army, National Cancer Institute, and International Aids Vaccine Initiative. Inovio's technology is protected by an extensive patent portfolio covering in vivo electroporation. More information is available at www.inovio.com.

An endless waiting game

<http://www.mykawartha.com>

By Lindsey Cole

William Catt's life seems like an endless struggle, filled with ups and downs, with no one there to help.

At the age of 17 he was taken to what was then Humber Memorial Hospital in Toronto for an operation to help him cope with crones disease. It was 1976 and there was no screening test for donated blood.

Mr. Catt needed two pints of blood during the operation.

Little did he know the blood that was being filtered into his body was tainted. He had no idea that years later he would be diagnosed with hepatitis C and would be stuck in limbo waiting for money which he says is rightfully his.

“I was stunned at first and then I just started talking to people and it led me to Jeff Leal and Dean Del Mastro.”

His reason for going to local politicians was simple, he says. He knew he was one of the 'forgotten' people.

In 2006, the federal government announced hepatitis C victims who were excluded from the previous compensation package handed out in 1998 will share \$1.1 billion in funding.

This compensation directly involves Mr. Catt as he is one of the people who contracted the virus before 1986.

Payments will range anywhere from \$30,000 to \$250,000 depending on the severity of the illness.

However, Mr. Catt hasn't seen his money.

The money was turned over to Crawford Class Action Services, who is currently handling when the money is handed out and to who.

“It doesn't make sense to me when your money is sitting around in a bank account. We could use that money now,” Mr. Catt says.

“My point of view of thinking is that they are going to wait until I'm dead.”

While calls to Crawford Class Action Services were not returned, the website states, “It is natural that those affected by a serious disease such as hepatitis C would wish to be compensated, and not want to wait indefinitely for that compensation to be paid.

“As the administrator of the pre-1986, post-1990 Hepatitis C settlement, Crawford Class Action Services' primary concerns are to ensure that all claimants are treated fairly, that claims for compensation are processed as expeditiously as possible, and that payment reaches the claimants at the earliest possible date.

“At the same time, Crawford must ensure the requirements of the settlement are met before payment is made.”

Mr. Catt says since September 2007 all they keep telling him is, “we're looking at your file.”

“This started in 2002 and it's 2008 and I'm no closer. I've talked to people in British Columbia, Peterborough here, Ajax, Owen Sound. They're going through the same thing.”

He says he has even tried local MP Dean Del Mastro, but since his first meeting with him in 2007, he hasn't been able to talk to him since.

“I've talked to his office,” he says.

According to MP Del Mastro, Mr. Catt's case is complicated, but he does understand his frustration.

“It is something that is moving forward. His case will be dealt with in the near term,” he says.

However, he says the independent agent is assessing payments based on the level of severity.

Those infected with hepatitis C are placed on a scale from one to six. Those who are at a level six are acutely ill and need the money before those who are classified at a lower level, he explains.

Another Peterborough man was a level five and recently got his settlement, MP Del Mastro notes, adding Mr. Catt is a level two.

“I would suggest that it is not going to be too much longer. It's been a long fight.”

However, for Mr. Catt, MP Del Mastro's comments provide little solace.

“He won't even talk to me. He's talked to me once. I left a message for two weeks straight. If he understood it (his situation) he would talk to me.”

MP Del Mastro said once parliament goes into recessed he would be happy to meet with Mr. Catt and reiterate to him the importance of filling out a form that would give his office the right to act on his behalf.

“We could contact him and asked to be regularly updated. We talked to Mr. Catt pretty much weekly since I was elected,” he says.

“He talked to my office pretty much once a week. They are instructed to work diligently on his behalf. I would certainly meet with him again if he liked. It is certainly not that I've avoided him. I would encourage him to contact the independent agent and get that form.”

However, Mr. Catt says he gets the run around every time he tries to address the issue.

“I'm stuck on where to go now. I'd just like to get this over with, put this all behind me,” he says.

“After everything is settled I get to live the rest of my life the way I can.”

For now he continues to go to Toronto for B-12 shots as well as hepatitis A and B vaccinations.

He continues to take upwards of 60 pills a day.

He continues to wait.

“Everyone seems to want to back out on me,” he says.

“There is no medication in the world that can cure Hep C. I’ll live day by day. I just want to get this over with.”

Hospitals reused syringes on 10,000 patients

<http://www.japantimes.co.jp/>

Kyodo News

The dubious practice of reusing syringes and other blood-collection devices at many medical institutions is raising concerns that HIV, hepatitis and other viral diseases may be spreading.

Reuse of the devices has been confirmed involving more than 10,000 people at nursing homes, nursing schools and medical institutions in at least 19 prefectures, sources said.

While actual harm has not yet been reported, the finding has prompted the health ministry to investigate.

In March 2006, the Health, Labor and Welfare Ministry issued a directive banning the practice in response to hepatitis infections caused by it in Britain. But the ministry was criticized for failing to fully disseminate the directive to medical institutions, and many hospitals were found to have reused blood-collecting devices in the belief that they are safe if sterilized.

Many cases involve a small device used by diabetics to measure blood-sugar levels. Easy to use and less painful, the device has become popular at hospitals but was originally intended for home use.

"It was unthinkable under normal circumstances," a Shimane prefectural official said, referring to a reuse case at a clinic in Masuda that surfaced May 21. The clinic used the same needles for at least 37 patients, including those infected with hepatitis B and C.

"We had assumed that the device would automatically replace the needles," said the clinic's chief, Hiroshi Ochi. However, a seal on the device clearly states that it cannot be used on multiple patients.

Vertex Sells Royalty Rights to HIV Drugs, Bets on Hepatitis C

<http://www.xconomy.com/>

Luke Timmerman

Vertex Pharmaceuticals is doubling down on its hepatitis C drug program. The Cambridge, MA-based company sold the rights to its royalty stream on two HIV drugs for a one-time payment of \$160 million in cash, which it will pump into its hepatitis C program. The HIV meds, Lexiva and Agenerase (both marketed by GlaxoSmithKline), are “non-core” financial assets, according to Vertex (NASDAQ: VRTX).

Vertex, with no marketed products of its own, is spending plenty of cash to get one for hepatitis

C. The company expects to lose \$380 to \$410 million this year, after starting the year with \$468 million of cash in the bank. That may sound like a lot of money to burn, but Wall Street analysts expect the drug to count Vertex's sales in the billions of dollars if trials of its lead experimental drug, telaprevir, succeed.

The company took a step toward that goal in March, when it started a final-stage clinical trial called Advance, which is enrolling more than 1,000 patients to demonstrate effectiveness of the drug.

The treatment, an oral pill, is designed to be more effective and more convenient than standard therapies. It is given for 24 weeks, instead of the nearly year-long course of therapy required on the conventional ribavirin and pegylated-interferon combination. Earlier, smaller studies showed telaprevir could cure almost two-thirds of hepatitis C patients, almost double the standard rate. The real proof of whether it's really that big of an advance will be in the results of the Advance trial.

June 5, 2008

Complete genome of a European hepatitis C virus subtype 1g isolate: phylogenetic and genetic analyses

<http://7thspace.com>

Hepatitis C virus isolates have been classified into six main genotypes and a variable number of subtypes within each genotype, mainly based on phylogenetic analysis. Analyses of the genetic relationship among genotypes and subtypes are more reliable when complete genome sequences (or at least the full coding region) are used; however, so far 31 of 80 confirmed or proposed subtypes have at least one complete genome available.

Of these, 20 correspond to confirmed subtypes of epidemic interest.

We presented and analysed the first complete genome sequence of a HCV subtype 1g isolate. Phylogenetic and genetic distance analyses reveal that **HCV-1g** is the most divergent subtype among the HCV-1 confirmed subtypes.

Potential genomic recombination events between genotypes or subtype 1 genomes were ruled out. We demonstrate phylogenetic congruence of previously deposited partial sequences of HCV-1g with respect to our sequence.

In light of this, we propose changing the current status of its subtype-specific designation from provisional to confirmed.

Author: Maria A Bracho, Veronica Saludes, Elisa Martro, Ana Bargallo, Fernando Gonzalez-Candelas and Vicent Ausina

Source: Virology Journal 2008, 5:72

Vertex rises on analyst look at telaprevir data

<http://biz.yahoo.com>

By Marley Seaman, AP Business Writer

Vertex climbs after Cowen analyst upgrades stock, expecting strong data on hepatitis drug soon

NEW YORK (AP) -- Vertex Pharmaceuticals Inc. shares jumped Thursday after an analyst predicted strong results and earlier approval of its hepatitis C drug candidate telaprevir.

Rachel McMinn of Cowen and Co. upgraded the stock to "Outperform" from "Market Perform." She expects clinical trial data to show that the addition of telaprevir makes standard treatments significantly more effective. As a result, she now thinks the drug will be launched in late 2010, rather than in 2011.

McMinn said the company will present data from a section of its mid-stage PROVE 3 trial soon, possibly as early as next week. The portion of the trial gave patients a combination of telaprevir and two standard drugs, Pegasys and ribavirin, for 12 weeks. They were then given Pegasys and ribavirin for 12 more weeks.

Patients in the trial had not previously been treated for hepatitis C.

McMinn expects the data to show that that dosing pattern is more effective than other analysts expected, as well as being better than standard treatment. She believes the results will lead analysts to raise their sales estimates.

"They've found 12 + 12 to be a very robust treatment arm," she said in a telephone interview, adding that the 12 + 12 trial design is also being used in late-stage studies of the drug.

McMinn also thinks positive data due out in the third quarter testing a twice-daily dosing regimen (compared with the current somewhat unwieldy thrice-daily dosage) will increase investor confidence on competitive concerns and on telaprevir's staying power in the market.

Shares climbed \$3.78, or 13.1 percent, to \$32.63, on twice average volume.

New case of Hepatitis C at surgery center

<http://www.kvbc.com>

LAS VEGAS (AP) -- Health officials say they're certain a patient contracted an acute case of Hepatitis C at an outpatient surgery center in Las Vegas, but they're not sure how.

A new report from the Southern Nevada Health District says there's not enough sufficient information to determine how the disease was transmitted at the Desert Shadow Endoscopy Center.

The facility formerly located on Burnham Avenue is associated with the Endoscopy Center of Southern Nevada. That clinic is known to have spread Hepatitis C to at least seven patients when

nurses reused syringes and vials of medication.

Desert Shadow patients are being encouraged to talk with their doctors about whether they should be tested for Hepatitis C, B, and HIV.

Officials estimate that more than 13,000 patients were treated at the clinic in the past two years.

Antibacterial wipes not too clean

<http://www.kvbc.com>

If you're one of the many who wipes down just about everything using antibacterial wipes, the Health Line 3 Team has some alarming news to pass along.

According to findings shown at the American Society of Microbiology's general meeting, antibacterial wipes may actually be spreading more dangerous bacteria than ridding you of them, if used more than once.

This study shows that while the wipes do kill some germs, a study of two hospitals show that the wipes could be transferring the so-called microscopic "super bugs" to other surfaces.

The main super bug, "MRSA" experts say, can cause life threatening infections.

Advice from experts is to use the wipes only once, on one surface at a time.

Hepatitis C Exposure Registry Up And Running

<http://www.ktnv.com>

On Thursday the Southern Nevada Health District announced it has wrapped up its investigation into the acute case of Hepatitis C.

Right now, health district officials say they know the acute case was linked to the Desert Shadow Endoscopy Center on Burnham Avenue.

They still do not know the source of the disease transmission, whether it was dirty syringes or other unsafe medical practices.

The Southern Nevada Health District cannot confirm the source of an acute case of hepatitis c.

It can say it is linked to the former Desert Shadow Endoscopy Center on Burnham Avenue.

"We have some information on the Burnham Clinic but not enough to make a solid recommendation for people to get tested. So we are encouraging people to talk to their physicians if they are concerned about their health and talk about getting tested with their physician," said Brian Labus, senior epidemiologist for the Southern Nevada Health District.

Health officials are hoping final lab tests from the CDC will arrive soon and help pin point an

exact cause.

A hepatitis c exposure registry is now in place and more than 60,000 former patients of Shadow Desert and the Endoscopy Center of Southern Nevada are encouraged to sign up.

"In collecting more information it will give us a better understanding of what occurred at the clinic," said Brian.

Attorney Robert Murdock who represents dozens of potential victims says the registry is a day late and a dollar short.

"This registry should have been set up immediately, they knew about this for a while. Why are we waiting until June? That does not make any sense to me," said Robert Murdock.

Murdock also wonders why the state medical board did not find it suspicious that these clinics were treating an outrageous number of people.

"Letting a clinic operate where they do procedures every seven minutes or so like building a car, we have to understand this is medicine. Somebody needs to come in and take a look at it, and see what they are doing," said Robert.

Mayor Oscar Goodman says by setting up an advisory committee among doctors, hospitals and community members they are already talking about pro - active measures to make sure this does not happen again.

Mayor Goodman along with the health district is urging anyone who think they have been exposed to get tested immediately and enroll in the hepatitis c exposure registry.

You can call 702 - 759 - 1393 for more information.

June 6, 2008

Genelabs Technologies Announces Presentation of Data on Non-Nucleoside HCV Polymerase Inhibitor at 3rd International Workshop on Hepatitis C, Resistance and New Compounds

<http://www.centredaily.com/>

REDWOOD CITY, Calif. — Genelabs Technologies, Inc. (Nasdaq:GNLB) announced that a presentation was made today at the 3rd International Workshop on Hepatitis C, Resistance and New Compounds in Boston, Mass. on a non-nucleoside hepatitis C virus (HCV) polymerase inhibitor discovered by Genelabs.

The oral presentation was given by Jill Bechtel, Ph.D. entitled, "In vitro antiviral activity and resistance profile of **GL60667 (NVP-LDI133)**, a potent non-nucleoside inhibitor of HCV NS5B polymerase." The presentation contains studies performed by both Genelabs and Novartis scientists in connection with a license and research collaboration commenced in June 2006 between Novartis and Genelabs, covering Genelabs' non-nucleoside HCV polymerase inhibitors.

GL60667 is one of a number of non-nucleoside HCV polymerase inhibitors discovered by Genelabs. In the presentation, Dr. Bechtel outlined the ability of GL60667 in vitro to reduce HCV RNA levels after prolonged (20 day) treatment, described combination HCV treatment studies with other HCV agents, and characterized the resistance profile of GL60667.

The treatment of replicon cells with 0.56 uM and 2.8 uM GL60667 for 20 days resulted in a 4-5 log reduction in HCV viral RNA. In addition, combination studies showed GL60667 was additive with interferon (alpha) or ribavirin in inhibiting HCV replication, whereas the combination with an NS3 protease inhibitor or a nucleoside NS5b inhibitor was synergistic. Sequencing of the resistant clones isolated from GL60667 selection revealed an NS5b mutation previously identified as a site for resistance to earlier compounds in this series. Interestingly, several clones had no mutations in the NS5b region. Sequencing of the entire replicon revealed several amino acid changes in NS3, NS4a, NS4b and NS5a. Transient assays using replicons bearing these mutations demonstrated that an amino acid change in the NS3 helicase domain reduced the susceptibility to GL60667 by 6.7 fold. Additional experiments demonstrated that this mutation only shifted the potency of a select number of compounds in this series leading to the identification of the region of the molecule responsible for the resistance.

"The data presented today from both Genelabs and Novartis scientists demonstrate potent antiviral activity for site 1 non-nucleoside HCV polymerase inhibitors alone or in combination with other HCV agents and a favorable resistance profile," said Ronald C. Griffith, Ph.D., Genelabs' Chief Scientific Officer. "This data clearly support the further investigation of site 1 NNI inhibitors for the future treatment of HCV infection."

About Genelabs Technologies

Genelabs is a biopharmaceutical company focused on the discovery and development of novel compounds for infectious diseases. In addition to a late-stage vaccine candidate for hepatitis E virus partnered with GlaxoSmithKline, the company is advancing multiple partnered and proprietary compounds designed to selectively inhibit replication of the hepatitis C virus. For more information, please visit www.genelabs.com.

Genelabs Technologies, Inc. Frederick Driscoll, 650-562-1477 Chief Financial Officer