

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Oct 4, 2008

## ***HIV, hepatitis tests urged for tattoo parlour clients***

<http://www.canada.com>

Star News Services

NIAGARA FALLS - Ontario health officials are urging people who received tattoos or piercings at two southern Ontario parlours this summer to undergo blood tests for HIV and hepatitis, after they were found to have used unsterilized equipment.

The Niagara public health department is searching for 40 customers of Venom Ink -- which has parlours in St. Catharines and Niagara Falls -- who may have been exposed to diseases during visits in July and August.

The health agency said there is a "low risk" that clients may have been exposed to HIV, hepatitis B and hepatitis C because non-sterilized equipment was used.

Oct 6, 2008

## ***Biolex Therapeutics Enters Into Agreement to Acquire Full Locteron(R) Commercial Rights***

<http://www.marketwatch.com>

PITTSBORO, NC, Oct 06, 2008 (MARKET WIRE via COMTEX) -- Biolex Therapeutics, Inc. announced that it has entered into an agreement with OctoPlus N.V. to acquire OctoPlus' 50 percent share of commercial rights to the **Locteron** product candidate for hepatitis C. Under the agreement, Biolex will take full responsibility for development and commercialization of Locteron. OctoPlus will retain a royalty interest in the product candidate and provide manufacturing and process development services to Biolex. The agreement calls for an up-front fee of \$11 million to OctoPlus and Biolex will pay up to \$138 million in additional development and sales milestones based on the progression of the product candidate through development and commercialization. Prior to entering into this agreement Biolex and OctoPlus shared the commercial rights to Locteron under a collaboration entered into in 2005.

"We look forward to rapidly advancing the development of Locteron and to maximizing its commercial potential," said Mr. Jan Turek, Biolex's Chief Executive Officer. "Biolex and OctoPlus have worked well on this program during the early stages of product development. As we progress toward more advanced clinical development, we determined that taking the lead on the development and commercialization of this product candidate would provide us the greatest opportunity to maximize the value of Locteron."

Locteron is a controlled-release interferon alfa designed to improve patient care in the treatment of hepatitis C through a more favorable side-effect profile and dosing convenience compared to existing pegylated interferon products. In contrast to Locteron's controlled-release mechanism, the currently approved products, Pegasys(R) and PEG-Intron(R), and the Albuferon(R) product candidate currently under development each are immediate release products that lack a controlled-release mechanism. Interferon alfa serves as the foundation of current combination

therapy for hepatitis C patients, and all major hepatitis C drug candidates currently in clinical trials are being studied in combination with interferon alfa. It is estimated that worldwide sales of interferon products for the treatment of hepatitis C will exceed \$5 billion by 2014.

Locteron combines BLX-883, a recombinant interferon alfa produced by Biolex in its patented LEX System(SM), with PolyActive(R), an advanced controlled-release drug delivery technology developed by OctoPlus. Locteron is configured to allow dosing once-every-two-weeks, an improvement in patient convenience compared to currently marketed pegylated interferon alfa products that require dosing every week. More importantly, Locteron's controlled-release mechanism results in the gradual release of interferon alfa to patients over the duration of two weeks. This controlled-release mechanism is designed to reduce the frequency, duration and severity of side effects, including flu-like symptoms, commonly experienced by patients treated with currently marketed pegylated interferons and with Albuferon. Locteron is currently in Phase 2 clinical testing.

Locteron is an investigational therapeutic candidate and has not been approved for sale by the United States Food and Drug Administration or by any international regulatory agency.

### **About Biolex Therapeutics**

Biolex is a clinical-stage biopharmaceutical company that uses its patented LEX System(SM) to develop hard-to-make therapeutic proteins and to optimize monoclonal antibodies. The LEX System is a novel technology that genetically transforms the aquatic plant Lemna to enable the production of biologic product candidates. The company's product candidates are designed to provide superior efficacy/tolerability profiles and to address large, proven pharmaceutical markets. Biolex's lead product candidate, Locteron(R), is in Phase 2 clinical testing for the treatment of chronic hepatitis C. Biolex has also developed two other product candidates that capitalize on the benefits of the LEX System which it is advancing toward clinical trials: BLX-155, a direct-acting thrombolytic designed to dissolve blood clots in patients; and BLX-301, an anti-CD20 antibody it is optimizing for the treatment of non-Hodgkin's B-cell lymphoma and other diseases.

*SOURCE: Biolex Therapeutics*

### ***Urgent need for action to tackle hepatitis C***

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

Madeleine Brindley, *Western Mail*

WALES faces an “explosion” in patients suffering liver failure if nothing is done to improve services for people with hepatitis C, experts have claimed.

Leading clinicians have criticised the Welsh Assembly Government for delaying the publication of a vital action plan for the disease.

The plan, which would outline improvements in community and hospital-based services for people with hepatitis C, was initially supposed to be published two years ago.

But despite further promises that it would be available at the end of last month, clinicians and support groups are still waiting.

Charles Gore, the chief executive of the Hepatitis C Trust, said: “This history of endless postponements is unacceptable. Patients need action, not promises.”

And Dr Ruth Alcolado, a consultant physician at the Royal Glamorgan Hospital in Llantrisant, said: “In 40 years’ time we will have an explosion of end-stage liver disease that will cost the taxpayer a fortune.

“Liver disease as a result of hepatitis C is slow and progressive, but in the future we could need a liver transplant centre or two in Wales.

“We are in a relatively privileged position at the moment as Wales’ numbers of hepatitis C are not as high as in England or Scotland.

“If we can start treating people and educating those at risk, then we can probably make a difference.”

Hepatitis C mainly affects injecting drug users in Wales, although a number of people developed the disease as a result of receiving contaminated blood products.

It is estimated that 0.5% of the UK population is affected – it is thought that 14,700 people in Wales are infected, but the majority are unaware.

The disease is more infectious than HIV and can be easily transmitted between people sharing drug paraphernalia, such as spoons for preparing drugs to be injected.

About one in five people with hepatitis C will develop cirrhosis of the liver, which can lead to end-stage liver failure.

There is no vaccine to prevent the infection, unlike other forms of hepatitis, although there are effective treatments available.

But Dr Alcolado said that services for people with hepatitis C, both in hospitals and the community in Wales, are “patchy”.

“Cwm Taf NHS Trust is a prime example – we have had a hepatitis C treatment service at the Royal Glamorgan for seven years, but there is no treatment going on in North Glamorgan.

“The only people being treated from North Glamorgan are those who have been picked up because they are already unwell and are referred to us.

“And for these people it means a couple of bus journeys for them every week, which can be a struggle.”

The Hepatitis C Trust said that the Welsh action plan was written and supposed to be published two years ago – former deputy health minister John Griffiths promised it would be published in

2006 during a National Assembly debate on hepatitis C; the National Public Health Service for Wales website said it would be published in the summer 2007.

And Health Minister Edwina Hart said in a written answer to a question from the Liberal Democrats that it would be published by the end of September.

It is understood the action plan will outline what community and hospital treatment services are needed, but it will also improve education for people at risk of hepatitis C and those who work with injecting drug users, such as needle exchange staff.

An Assembly Government spokesman said: "Mrs Hart is committed to meeting the challenge of blood-borne viral hepatitis and ensuring we address the public health issues.

"A significant amount of work has been undertaken in the development of an action plan.

"Officials have worked with the NPHS to refine the plan, to prioritise its recommendations and to consider where future investment would make the most immediate impact.

"The process for setting budget allocations for 2009-10 and beyond is under way and the costs and timetable for implementing the plan is being considered in that process.

"The minister expects to publish the plan for consultation in the coming weeks."

### ***Vitamin D Deficiency Prevalent in Patients with Chronic Liver Disease***

<http://www.eurekalert.org/>

Researchers from the University of Tennessee in Memphis measured the vitamin D levels of 118 chronic liver disease patients. Researchers found 92.4 percent of chronic liver patients had some degree of vitamin D deficiency and at least one third were severely deficient. Severe vitamin D deficiency was more common among cirrhotics.

"Since deficiency is common among these patients, Vitamin D replacement may hopefully prevent osteoporosis and other bone complications related to end stage liver disease," said lead researcher Dr. Satheesh P. Nair.

The study included 43 hepatitis C patients with cirrhosis; 57 hepatitis C patients without cirrhosis; 18 cirrhosis patients without hepatitis C. The severity of vitamin D deficiency was divided into three groups: mild (between 20-32 ng/ml), moderate (between 7-20 ng/ml), and severe (less than 7 ng/ml).

#### **Importance of Vitamin D and Bone Health**

Vitamin D, a fat-soluble vitamin, helps the body absorb calcium and plays a crucial role in the growth and maintenance of strong, healthy bones. A lack of vitamin D causes calcium-depleted bone, which can weaken the bones and increase the risk of fractures resulting from osteoporosis.

A diet rich in vitamin D, such as fish, eggs, fortified milk, and cod liver oil, is essential to maintaining good bone health.

## About the American College of Gastroenterology

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 10,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical, and cost-effective health care to gastroenterology patients.

Oct 7, 2008

## ***Antiretroviral therapy does not fully reverse impact of HIV on hepatitis C-related cirrhosis***

[www.aidsmap.com](http://www.aidsmap.com)

David McLay

In a meta-analysis of over 3500 patients co-infected with HIV and hepatitis C, Canadian researchers have found that the risk of hepatitis C-related cirrhosis has fallen since effective antiretroviral therapy became available. However, the report, published in the October 1st edition of *AIDS*, also notes that antiretroviral therapy does not fully counter the harmful impact HIV has on the liver of co-infected individuals.

HIV and hepatitis C virus are both spread through blood-to-blood contact, and so co-infection can be common, especially among certain groups such as injecting drug users. The risk of hepatitis C transmission during sex is low, though outbreaks of co-infection have been seen in large urban centres in western Europe among gay men who practise rough sex. Mother-to-child transmission of hepatitis C is also uncommon, but the risk is increased in the presence of HIV co-infection.

Hepatitis C targets the liver, which becomes progressively damaged through fibrosis (moderate scarring). Cirrhosis (severe scarring) normally takes several years to develop, but there is evidence that being co-infected with HIV increases the risk of developing advanced liver disease. In people who only have hepatitis C and not HIV (hepatitis C mono-infection), the average time to liver disease is about 30 years. Studies in co-infected people report average times of 15 to 25 years. The cause of this hastened fibrosis is not clear, but may be linked to the immunosuppression caused by HIV.

Antiretroviral therapy can effectively suppress HIV replication and leads to improvements in the immune function in HIV-positive people. It remains unclear whether or not effective HIV treatment has blunted the impact that HIV has on hepatitis C disease. In meta-analysis, performed before effective antiretroviral therapy became available, co-infection was associated with a 2.9-fold increase in risk of cirrhosis compared with hepatitis C mono-infection. More recent studies have provided conflicting results on the benefits of HIV treatment. Antiretroviral therapy has been linked to lower liver-related death rates, but it is not clear that it slows fibrosis.

To address this question, investigators at the University of Toronto conducted two meta-analyses of studies of co-infection published between 1990 and 2007. In the first, they used 17 studies of co-infected people from the US and Western Europe to estimate rates of disease progression. In the second, they collected data from 27 studies of both hepatitis C mono-infected and

HIV/hepatitis C co-infected people and assessed the risk of cirrhosis and the impact of antiretroviral therapy on this risk.

To get a sense of how quickly liver disease progresses in co-infected people, the investigators analysed data from over 3500 co-infected people, over 80% of whom had contracted hepatitis C through injecting drug use. They found that the proportion of co-infected people who had cirrhosis was 21% after 20 years, and 49% after 30 years. This finding is similar to some 20-year estimates from some studies of hepatitis C mono-infection (22% to 24%), but much higher than estimates from other studies (4% to 7%), they write.

The investigators then turned their attention to the impact of antiretroviral therapy on hepatitis C-related liver disease. Using the second data set of 27 studies including over 7600 people, they calculated and compared the risk of developing cirrhosis between HIV/hepatitis C co-infected (2636 patients) and hepatitis C mono-infected (4970 individuals) groups. They also evaluated the impact of antiretroviral therapy on the risk of cirrhosis.

The investigators found significant variations in the relative risks reported in the studies, but overall, outcomes were worse among co-infected people compared to those with hepatitis C alone. The estimated risk of cirrhosis was 2.11-fold higher (95% CI 1.51 – 2.96) with co-infection than with hepatitis C mono-infection. The risk was 2.49-fold higher (95% CI, 1.81 – 3.42) in co-infected people not taking antiretroviral therapy and 1.72-fold higher (95% CI, 1.06 – 2.80) in those on HIV treatment.

“Over the period studied, HAART [highly active antiretroviral therapy] did not appear to fully correct the adverse effect of HIV infection on [hepatitis C virus] prognosis,” the investigators write. They note that only about three-quarters of people included in the on-antiretroviral therapy analysis had been on treatment for over a year and thus, the risk estimates may be based on a suboptimal response to such therapy. “In addition,” they offer, “HAART may have dual effects, producing slower fibrosis progression as a result of immune reconstitution, but also inducing liver toxicity, which may lead to an enhancement of fibrogenesis.”

In a final analysis, the investigators tested the assumption that the rate of fibrosis progression remains constant over time in co-infected people. This assumption has weakened estimates of progression rate and made comparison between studies difficult. The investigators calculated the annual probability of transitioning through the different stages of fibrosis. Using two different statistical analyses, they concluded that in co-infected individuals, the rate of progression is constant, with an estimated weighted mean transition probability between 0.11 and 0.12 per year at any stage of fibrosis.

Concluding, the investigators offer that their findings provide insight to some very practical questions about caring for a HIV/hepatitis C co-infected population. “These estimates,” they write, “should provide more accurate information for the prediction of [hepatitis C] disease burden, economic evaluation of antiviral therapies and preventive strategies, and healthcare policy decision-making among the injecting drug user population.”

## Reference

Thien HH, et al. Natural history of hepatitis C virus infection in HIV-infected individuals and the impact of HIV in the era of highly active antiretroviral therapy: a meta-analysis. *AIDS* 22:1979 – 1991, 2008.

## ***Experts Unite in New York; Discuss Hepatitis C and New Treatment Developments***

<http://www.medadnews.com>

WHAT: Science Writers' Workshop on Hepatitis C: The Hidden Epidemic hosted by the Hepatitis Foundation International

WHEN: Thursday, October 16, 2008

WHERE: New York Academy of Sciences in Manhattan

WHO: Clinicians, researchers and patients will join the Hepatitis Foundation International for this important discussion about hepatitis C and promising therapies on the horizon.

Keynote speakers include:

- Ira M. Jacobson, MD Medical Director of the Center for the Study of Hepatitis C Professor of Clinical Medicine Weill Cornell Medical College of Cornell University
- Raymond S. Koff, MD Clinical Professor of Medicine University of Connecticut School of Medicine

WHY: As the nation's most common blood-borne infection and one of the most significant health problems affecting the liver, hepatitis C is estimated to affect some 4 million Americans in its chronic form. It is the leading cause of chronic liver disease, death from liver disease and liver transplant. While advances in medicine and treatment have been made, disease management remains a challenge for many patients.

Today, the treatment of hepatitis C stands squarely on the verge of a major breakthrough. New therapies in late stage development show high and lasting viral clearance rates, better patient tolerability and shorter treatment duration.

Come hear more about these exciting new advances from the experts in advance of the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in October.

RSVP: Marissa Nelson 212-477-9007 ext. 21 [mnelson@bmccommunications.com](mailto:mnelson@bmccommunications.com)

Source: *Hepatitis Foundation International*

Web Site: <http://www.hepfi.org/>

**Oct 8, 2008**

## ***Former Hartford Mayor Recovering After Surgery***

<http://www.courant.com>

By Jeffrey B. Cohen

Former Mayor Mike Peters — restaurateur, Hartford booster and former firefighter — underwent a nearly eight-hour liver transplant early Tuesday and is recovering at Hartford Hospital.

As of Tuesday afternoon, Peters, 59, was listed in critical, but stable condition and his doctors said they were pleased with the initial results. They say Peters could remain in the hospital another week or more.

Diagnosed with cirrhosis, Peters had considered various options — including a partial transplant from a relative, or a full transplant from an unrelated, brain-dead donor. In the end, a donor liver became available and Peters went to Hartford Hospital about noon Monday, family friend Pat Ryan said. The surgery didn't begin until 3 a.m. Tuesday, ending at about 10:30 a.m., Ryan said.

"He's out, he's doing well. The surgery was as successful as it could be, and we're all hoping for the best," Ryan said after the procedure.

The most common reason in the U.S. for a liver transplant is liver failure due to chronic hepatitis C, according to Dr. George Wu, a professor of medicine and the director of the Hepatology Center at the University of Connecticut Health Center. Another major cause is alcohol use, Wu said.

As of last Friday, 87 people were awaiting livers from transplant centers in Connecticut, according to a spokeswoman for the Organ Procurement and Transplantation Network.

Although the exact origin of Peters' disease is unclear, the former mayor has never been bashful about drinking, once telling a reporter, "I am who I am. I didn't take an oath of sobriety." After his diagnosis, however, Peters stopped drinking entirely — both to preserve the health of his ailing liver and improve his chances of getting a new one, Ryan said.

Dr. Matt Brown, one of Peters' two surgeons, said that the transplant center at Hartford Hospital requires people with a history of drinking to abstain for six months before the transplant.

Brown said he got word Monday that a donor liver was available at a hospital in central Connecticut. As he removed the liver from the younger, brain-dead person, his partner, Dr. Anne Lally, prepared Peters — who, by virtue of objective medical scoring and his proximity to the donor — was at the top of the candidate list.

The former mayor would eventually get three long incisions in what Brown called "a massive operation." When he saw Peters' liver, Brown said, it was clear the former mayor was in the advanced stages of illness.

After the surgery, Brown visited Peters, who was on a ventilator, but responsive — shaking his head and squeezing the doctor's hand when asked.

"But it's not like he's up there doing crossword puzzles," Brown said.

Peters left office in 2001. He has said he is considering a run for mayor in 2011.

## **Compass in calls for industry-wide Hep C guidelines**

<http://ftadviser.com>

Joy Dunbar Magazine

*Life assurance industry is burying its head in the sand over this issue, says managing director*

Each life assurance company is writing their own rules around Hepatitis C and there are no existing industry guidelines, according to Chris Morgan, managing director of Compass.

Mr Morgan said given the problems that the insurance industry had around Hiv, which is equally as sensitive, this is quite astonishing.

Mr Morgan said: "Once again, the life assurance industry is burying its head in the sand over an issue that could seriously affect its risk pool. Our recent research concludes that each company has very different ideas on how each applicant with Hep C should be treated.

"We have contacted the Association of British Insurers, and it has confirmed that it currently has no guidelines for the way that Hep C is treated within the life assurance industry. When you consider that an estimated 500,000 people in the UK are currently affected by Hep C, this is somewhat remarkable."

Mr Morgan added the ABI has made a great effort to ensure that the underwriting practices around Hiv are now fair and non-intrusive. The HIV expert working group has since been disbanded and replaced by a new expert advisory group on health and insurance.

Compass, which provides financial services to the gay community, is urging the ABI to take a closer look at the underwriting of Hep C, and ensure that applicants are treated with respect - and without intrusive questions. It added the knowledge gained from the removal of discrimination around HIV could prove invaluable in looking after people living with Hepatitis C.

A spokesman for the said: "Insurers are acutely aware of the issues around diseases like Hep C and do treat customers sensitively and with respect. The ABI has been doing a lot to improve how gay men are treated when applying for life insurance products - for example, you will not be asked if you are gay or if you have had tests for sexually transmitted diseases.

"If you have had a test for Hep C with a negative result then you do not need to tell your insurance company and this will not be taken into account. If you have been diagnosed with Hep C or HIV then often this will require specialist medical underwriting. The best way to find the right cover in these cases is to go to a specialist insurer or use an insurance broker."

## **Serum Ribavirin Level Impacts Outcome in HCV-HIV Coinfection**

[www.medscape.com](http://www.medscape.com)

NEW YORK (Reuters Health) Oct 08 - The serum concentration of ribavirin influences the outcome of treatment of hepatitis C virus (HCV) genotype 1 or 4 infection in HIV-positive patients, results of a study indicate.

A ribavirin concentration of 2,300 ng/mL or less is a "strong predictor of nonresponse" in this patient population, the study team notes in the September issue of the *Journal of Medical Virology*.

Measuring serum ribavirin concentrations in these "difficult-to-treat patients could be used to optimize the ribavirin dose and so increase the probability of success," Dr. Florence Nicot from INSERM, Toulouse, France and colleagues conclude.

They investigated the relationship between serum ribavirin and pegylated interferon concentrations 3 and 6 months after the start of treatment, and treatment outcome in 35 HCV-HIV coinfecting patients.

The serum levels of interferon were similar at 3 and 6 months, as were levels of ribavirin, although levels varied widely between patients.

Results showed no influence of the pegylated interferon concentration on treatment outcome, which is in keeping with a recent study, the authors note.

The ribavirin concentrations, on the other hand, tended to be higher in responders (2,322 ng/mL) than nonresponders (1,833 ng/mL). Moreover, responders infected with HCV genotype 1 or 4 had significantly higher ribavirin concentrations (2,672 ng/mL) than did similarly infected nonresponders (1,758 ng/mL).

"The ribavirin concentration could be important for predicting treatment outcome in patients infected with HIV and HCV genotype 1 or 4," Dr. Nicot and colleagues conclude.

In their study, a ribavirin concentration of 2,300 ng/mL was the best threshold for predicting a nonresponse in these patients, they note, adding that 86% of the patients with a concentration below this threshold were nonresponders.

*J Med Virol* 2008;80:1523-1529.

### **FDA Safety Changes: Baraclude**

[www.medscape.com](http://www.medscape.com)

October 9, 2008 — The US Food and Drug Administration (FDA) has approved safety labeling revisions to advise of the risks for lactic acidosis and severe hepatomegaly in patients receiving treatment with nucleoside analogues, including entecavir; the potential for hepatotoxicity associated with lapatinib therapy; and the risk for dystonia in patients treated with antipsychotic agents such as clozapine.

Entecavir (Baraclude) Linked to Risk for Lactic Acidosis and Severe Hepatomegaly

On July 25, the FDA approved safety labeling revisions for entecavir (Baraclude tablets and oral solution; Bristol-Myers Squibb Co) to provide updated information regarding the risks for lactic acidosis and severe hepatomegaly in patients receiving treatment with nucleoside analogues.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination with antiretroviral therapy.

According to the FDA, the majority of cases have occurred in women; obesity and prolonged nucleoside exposure may also be risk factors. Although particular caution is advised when administering nucleoside analogues to patients with known factors for liver disease, some cases have been reported in patients with no known risk factors.

Entecavir therapy should be suspended in patients in whom clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, which may occur in the absence of marked transaminase elevations.

Entecavir is a nucleoside analogue indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferase levels or histologically active disease.

### ***Genelabs Technologies Announces Presentation of Data on Non-Nucleoside HCV Polymerase Inhibitor at the 15th International Symposium on Hepatitis C Virus and Related Viruses***

<http://www.centredaily.com>

REDWOOD CITY, Calif. — Genelabs Technologies, Inc. (Nasdaq:GNLB) announced that three presentations were made at the 15th International Symposium on Hepatitis C Virus and Related Viruses, each on a non-nucleoside hepatitis C virus (HCV) polymerase inhibitor discovered by Genelabs.

The presentations focused on the discovery, in vitro antiviral activity, resistance profile, pharmacokinetics and mechanism of action of **GL60667** (NVP-LDI133), a potent non-nucleoside inhibitor of the HCV NS5B polymerase. The presentations contain studies performed by both Genelabs and Novartis scientists in connection with the license and research collaboration commenced in June of 2006 between the companies, covering Genelabs non-nucleoside HCV polymerase inhibitors. GL60667 is one of a number of non-nucleoside HCV polymerase inhibitors discovered by Genelabs.

"The presentations made describe the discovery of new site 1 non-nucleoside polymerase inhibitors with potent anti-HCV activity" said Ronald C. Griffith, Ph.D., Genelabs' Chief Scientific Officer. "Other compounds from this class continue to advance forward in preclinical studies and we are very pleased with the progress made to date."

#### **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 both partnered and proprietary compounds designed to selectively inhibit replication of the hepatitis C virus. For more information, please visit [www.genelabs.com](http://www.genelabs.com).

## **Longing For A Liver**

<http://www.morningsun.net>

Nikki Patrick

*The Morning Sun*

*Larry Holliday's tattoo 35 years ago may have given him Hepatitis C, and now Holliday needs a liver transplant*

PITTSBURG — Back on 1969, Larry Holliday, Pittsburg, got a tattoo. But that's not all he got.

“That's probably when I contracted hepatitis C, in a tattoo parlor in back of a bar in Fort Worth, Texas, and it's taken 30 years to catch up with me,” Holliday said. “I paid \$35 to have my life taken away from me.”

He first realized something was wrong on June 19, 2006.

“I thought I was having a heart attack, My blood platelet count just went haywire, and I had severe edema. They had to draw off the fluid,” Holliday said.

Finally, after a lot of blood tests, Holliday learned he had hepatitis C.

“I did fine for a year, but some people with hepatitis C develop liver cancer,” he said. “We went to another doctor in Joplin and I had a CAT scan, MRI and a liver biopsy, and the doctor found cancer.”

On June 16, 2008, he was told that he had one year to live.

“I went to the University of Nebraska Medical Center on July 7 for a transplant evaluation,” Holliday said. “They needed to find out if I was able to handle the transplant surgery. Now it's just a matter of when a liver comes in.”

When the call does come, Holliday and his wife, Phoebe, will have 46 hours to get to Omaha, possibly by car, since it would be difficult and expensive to arrange a flight there. The surgery itself will cost between \$325,000 and \$330,000, not to mention the expenses of Mrs. Holliday staying in Omaha with her husband for six to eight weeks.

“They have a hotel at the hospital that costs \$500 a month.” Mrs. Holliday said. “That's about the cheapest thing we can find.”

She's a lifetime Pittsburg resident.

“We're living in my grandmother's house,” she said. “I worked in Woolworth for years, over in the knickknack section.”

Her husband was born in Alameda, Calif., where his father was stationed at a U.S. Navy base, and attended San Francisco State University. A Vietnam veteran, he moved to Pittsburg 35 years ago.

“I worked 29 years with Dickey and Mission Clay, and also worked at New Horizons,” Holliday said. “Now I’m just waiting on a telephone call from Omaha.”

But he does have a message he wants to get out to young people — or anybody else — who’s thinking about getting a tattoo or piercing.

“A lot of people think they’ve sterilized the needles used, but it only takes one speck of blood to spread disease,” Holliday said. “There are many viruses floating around out there, and you don’t know if the previous person that needle was used on had AIDS or hepatitis. Go ahead and get a tattoo or piercing if you want to be like me, but not if you want to live to a ripe old age.”

A fund for Holliday’s expenses has been established at the Kansas Teachers Community Credit Union.

**Oct 10, 2008**

## ***Alcohol not only cause of cirrhosis***

<http://www.baltimoresun.com>

By Holly Selby

Nearly 17.6 million adults in the United States are alcoholics or have an alcohol problem, according to the National Institutes of Health. Between 10 percent and 20 percent of heavy drinkers develop cirrhosis of the liver, which is the 12th leading cause of death by disease. But alcoholism is not the only risk factor for this disease, says Dr. Paul Thuluvath, medical director of the Institute for Digestive Health & Liver Diseases and the director of the Center for Liver & Biliary Diseases at Mercy Medical Center.

### **What is cirrhosis?**

The liver is the largest organ in the body. Whenever there is inflammation in the liver, the body tries to heal itself, and, in the process, forms scar tissue. As more scar tissue forms, the entire liver becomes shrunken and nodular. Most of the liver cells disappear, and the organ becomes mostly scar tissue with liver cells in between.

### **What are the risk factors for cirrhosis?**

Cirrhosis can be due to many causes, but the most common is alcohol - if a man drinks more than three drinks a day or a woman drinks more than two drinks a day, that is considered excessive. Only a minority of people who drink like that will develop cirrhosis, but the numbers are high when you look at how many people drink in excess.

The second most common cause is hepatitis C. We have about 4 million people in the United States with hepatitis C, and 20 percent of those patients with hepatitis C will progress to cirrhosis. Hepatitis B (which affects about 1.25 million people) is a major cause of cirrhosis and liver cancer among immigrants from Asia and Africa.

Among the other causes also is what we call nonalcoholic fatty liver disease (NAFLD). This is mainly caused because the people in this country and elsewhere in the world are becoming more and more obese, and develop diabetes (insulin resistance), and high cholesterol and triglycerides. This is a disease potentially preventable by diet and exercise.

### **What are the symptoms of cirrhosis of the liver?**

Most people in the early stages will experience no symptoms at all. The diagnosis frequently is missed for that reason. But early symptoms could include fatigue and minimal swelling in the legs. And in blood tests, doctors might find some elevation in the liver enzymes, and sometimes low albumin and low platelets.

As the disease progresses, the patient will develop swelling of the abdomen because of fluid accumulation and may experience sleep disturbances, confusion and memory loss. Bleeding from the stomach (vomiting blood or [having] black stools) is a serious, life-threatening complication. They also could develop liver cancer.

### **Is this a fast-progressing disease?**

Most of the conditions that might cause it - such as hepatitis C and nonalcoholic fatty liver disease - progress fairly slowly over a period of 10 to 30 years.

But certain conditions, such as the disease when caused by drinking excessively or autoimmune hepatitis (in which the immune system attacks the liver cells), can progress more rapidly.

### **Is cirrhosis treatable?**

Most of these conditions that predispose people to develop cirrhosis are treatable. Sixty percent of hepatitis C patients can be treated with medicine, and if treated early enough, they may not progress to cirrhosis. Even those in the early stages of cirrhosis can heal. Similarly, hepatitis B is treatable in most people these days. Many other conditions that cause liver disease, such as autoimmune hepatitis, hemochromatosis (too much iron in the liver) and Wilson's disease (too much copper), are potentially treatable if diagnosed early.

In cases involving alcohol, there is no medication. If the person stops drinking, however, the liver can regenerate, but the person has to stop drinking completely.

One area in which we still do not have good treatment is the nonalcoholic fatty liver disease (NAFLD). The only thing to do is to lose weight, which is sometimes very difficult to do.

### **What do patients with liver disease need to know?**

Early detection is important. Early diagnosis can lead to better prognosis, as the liver can regenerate. Advanced cirrhosis can only be managed by liver transplantation.

All doctors (particularly family physicians, pediatricians and internists) need to recognize that even minimal changes in liver enzymes can mean significant disease. ... Many doctors will say, "Come back in six months or a year," and then it is too late.

People who are at high risk [for hepatitis] - because of IV drug use, transfusion, multiple sexual partners - should be screened for hepatitis B and C. And everyone, and especially those with liver disease, should get vaccination for hepatitis A and B.

*Holly Selby is a former reporter for The Baltimore Sun.*

## **Doctor blamed in case of infected IHC carer**

<http://www.stuff.co.nz>

The Dominion Post

A doctor's failure to check up on a basic blood test led to a community care worker contracting hepatitis B and needing a liver transplant, a court has been told.

A week-long Labour Department prosecution of Idea Services was completed in Napier District Court yesterday and the judge has reserved his decision.

The department alleges that Idea Services, the community-service branch of IHC, failed to take all practicable steps to prevent a Hastings employee from being exposed to hepatitis B.

A female carer contracted the disease after being bitten by a patient in May last year. The carer, whose name is suppressed, suffered acute organ failure and needed a liver transplant.

The patient was a known carrier of hepatitis B and the carer was aware of this, but believed she was immune because she had been vaccinated in 1999 at the company's expense.

However, she had had only one of three required vaccinations to ensure immunity. The worker says she was not told that three vaccinations were needed.

The department says Idea Services should have confirmed her immunity before putting her in a high-risk situation.

Labour Department lawyer Natasha Szeto said there had been several opportunities for the company to screen the employee's blood.

The carer had been bitten by the same patient in January last year and had seen a Hastings doctor who tested her for hepatitis B immunity - but the carer was never contacted with test results.

Judge Geoff Rea suppressed the Hastings doctor's name, noting that he had not had the opportunity to provide evidence.

Judge Rea questioned whether the company could be held accountable when screening had in fact taken place but a "lack of communication" had meant the results had not been passed on.

The tests "came back that she was not immune, but no one bothered to tell her" or her employer, Judge Rea said.

"The doctor had a big sign up in the waiting room saying 'don't ring us, we'll ring you' and that's what she [the carer] did. Any of us in that position would assume there was nothing wrong, otherwise the doctor would have called me."

Four medical experts giving evidence were critical of the doctor's treatment.

Idea Services lawyer Bruce Corkill said a company employee asked the carer about the blood tests and was told they were with the doctor.

### ***Viral Hepatitis C support group to begin meeting***

<http://www.rocklintoday.com>

AUBURN, CALIF –Placer County Health and Human Services will begin hosting a hepatitis C support group for anyone who wants to know more about the disease and its treatment. The confidential group is offered at no cost, is open to the public and will meet from 4:00 to 5:00 p.m. in the Placer County Community Health Large Conference Room, 11484 B Ave., in Auburn.

The first meeting is Wed., Oct. 15, 2008, with additional meetings scheduled for Oct. 29, and Nov. 12 and 19, from 4:00 p.m. to 5 p.m. A second group is expected to begin later this year. Each meeting will focus on one topic and will be moderated by county staff that regularly works with communicable diseases.

Hepatitis C is a contagious liver disease that results from infection with the hepatitis C virus. Hepatitis C is usually spread when blood from an infected person enters the body of someone who is not infected. Most people become infected with the hepatitis C virus by sharing needles or other equipment to inject drugs. The virus can also be transmitted to those who receive tattoos or piercings in a setting that has poor infection control practices. Additionally, persons who received blood product for clotting problems made before 1987, or blood transfusions before 1992 may have increased risks for the disease.

Hepatitis C can be either “acute” or “chronic.” Acute hepatitis C virus infection is a short-term illness that occurs within the first 6 months after someone is exposed to the hepatitis C virus. For most people, acute infection leads to chronic infection. Chronic hepatitis C is a serious disease that can result in long-term health problems, or even death. Many of those infected do not realize they have the disease.

For additional information about the Placer County group meetings, please email or call to RSVP, Candace Jones (530) 889-7184 [cnjones@placer.ca.gov](mailto:cnjones@placer.ca.gov) or Dennis Cain (530) 889-7120.

For more information about the hepatitis C virus, visit the Centers for Disease Control and Prevention’s hepatitis C website: <http://www.cdc.gov/hepatitis/HepatitisC.htm> or the California Department of Public Health’s hepatitis C website: <http://www.cdph.ca.gov/HealthInfo/discond/Pages/HepatitisC.aspx>.

### ***Ailing deputy withdraws grievance after county approves leave, insurance***

<http://www.southmacoupin-news.com>

A Macoupin County Sheriff's deputy who was terminated two weeks ago has withdrawn his grievance against Sheriff Don Albrecht after reaching an agreement that provides him with a 12-month leave of absence and paid insurance coverage for two months.

"I'm very happy with the way things turned out," said Bill Bort, an 18-year veteran of the Sheriff's Department, who is ill with end-stage liver failure resulting from hepatitis C contracted in infancy.

Bort has been away from his job as a courthouse security officer since June 24 when the progression of his disease left him unable to work. He is currently on a waiting list for a liver transplant and has hopes of returning to his old job after the surgery.

Albrecht reportedly denied Bort's first request for a medical leave of absence in May. Bort subsequently sought insurance coverage under the Family Medical Act which expired on Wednesday, Sept. 24. On Monday, Sept. 22, Bort sent another written request to Albrecht asking him to approve an unpaid leave of absence. On Wednesday, Sept. 24, a deputy reportedly went to Bort's home in Carlinville with a letter denying the leave of absence and terminating Bort's employment as of Thursday.

The Policemen's Benevolent Labor Committee, which was certified to represent Sheriff's Department employees last month, filed the grievance on Friday, Sept. 25, the day after Bort's termination was effective.

PBLC Labor Representative Teresa L. Heisel said she was "extremely happy with the outcome" of a meeting last Tuesday with her, Bort, Albrecht and Macoupin County Board Chairman Andy Manar. But she continues to question the actions that led up to the grievance filing.

"It's unfortunate we had to get about it the way we did," she said. "The Sheriff indicated he already had an agreement worked out for Bill. Whether or not that is true or sincere, I saw this as a job to be done. If it was true, why didn't anybody tell Bill Bort that that it was so? The communication could have been a whole lot better."

Allowing Bort to believe he was terminated and without health care coverage, she said, caused unnecessary stress for Bort.

"When things are as frustrating as they are, something like this just completely stops you," Bort agreed. "I've never seen someone get fired because his boss was trying to help him out. In 18 years with the Sheriff's Department this is the first time I had to go to my union. I had to fight for what I thought I deserved."

Albrecht, however, said the filing of the grievance prevented him from telling Bort about the arrangements he was able to make on Bort's behalf.

"The story is in the timeline," Albrecht said.

Because of the Health Information Privacy Protection Act, Albrecht said he is precluded from discussing the specifics of Bort's health issues. But he said the Sheriff's Department has been dealing with the problem for the past two years.

“He was always afforded time off for his needs,” Albrecht said.

After Bort left the job in June for health reasons, it became apparent that he would run out of accrued time off on Sept. 24, the Sheriff said. Under the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA), employees who have health insurance as part of their benefits package are entitled to buy the same insurance for up to 18 months after leaving their employment at the same price paid by their employers.

The catch is that employees have to pay for the coverage out of their own pocket, Albrecht said, “and it's very expensive.”

The Sheriff's Department employees were represented by the Fraternal Order of Police in May when Bort first asked for a medical leave of absence. At that time, Albrecht said he told Bort that he hoped he would be able to find alternative insurance coverage. Bort's wife, Mary, has family insurance coverage through her job, but Bort is ineligible for coverage under that policy until November.

With his county benefits expiring at the end of September, Bort would have been without coverage for about two months while yet awaiting a liver transplant.

“When it came close to Sept. 24, I realized there wasn't much choice but to terminate him,” Albrecht said.

Albrecht challenged the union's characterization of his action as a “firing.”

“Termination, to me, is not a firing,” he said. Bort was not terminated for cause, Albrecht insisted. “There was nothing that was the fault of Bill Bort other than he just ran out of time.”

He said he did not grant an unpaid leave of absence because it would have been an “hollow gesture because it wouldn't have included any health insurance.”

Before the grievance was filed, Albrecht said he contacted County Board Chairman Manar to “see if we could look at this on a case-by-case basis” and do something to help Bort.

“He said, ‘Absolutely, we'll talk about it,’” Albrecht said. Manar called a meeting of the County Board's Finance Committee on Sept. 25, according to Albrecht, and the committee gave Albrecht and Manar power to act in offering Bort two months of paid insurance coverage.

“Before I could call Bill, the union filed a grievance which stopped me from talking to him,” Albrecht said. “We felt this could have been resolved without union intervention. A simple phone call to me could have cleared this up because the County had resolved the problem before the grievance was filed.”

Bort and Heisel, however, believe the grievance was a necessary tool.

“If it weren't for my union and County Board Chairman Andy Manar, who was at the grievance hearing, I would not have the package I've got,” Bort said.

Bort said the unpaid leave of absence extends to Sept. 28, 2009, at which time he could return to work if his health permits it.

“I’m still a deputy and I have a right to return to work after my transplant,” he said. “My pay structure, my seniority, everything stays intact.”

Without the leave of absence, Heisel said Bort would have had to reapply for the position if he is able to return to work and would have lost his seniority.

In addition to the leave of absence, the county is picking up the tab for two months of insurance under COBRA until Bort can sign onto his wife's policy.

Bort said he apparently contracted hepatitis C as an infant. His parents had mismatched Rh factors, which required Bort to undergo six complete blood transfusions in as many days as a newborn.

“I contracted it there,” he said, though symptoms of the disease did not appear until about 12 years ago. In the past 12 years, he said he has undergone a series of seven treatments for the disease.

“That rug was yanked out from under my feet this year,” he said, when doctors told him he was a “non-responder” to available treatments. The frequency of his illnesses increased from once every three months to “a week out of every three weeks.”

“The writing is on the wall,” he said. “A liver transplant is my only hope.”

He said he is scheduled to visit Mayo Clinic in December for further evaluation and a determination on where on the waiting list he will be positioned.

“My doctor told me there's a better guarantee on concrete than there is on a liver transplant,” Bort said. “With a liver transplant, there's no guarantee you're going to get one, there's no guarantee your body is not going to reject it and there's no guarantee you'll be able to return to work.”

A major symptom has been extreme fatigue, which worsened to the point that he could no longer function in his capacity as a security officer at the courthouse. After a wrestling match with a belligerent suspect left him weak and drained, Bort decided it was time to hang up his uniform.

“You get two or three hours of good time a day before your body says, ‘Hey, it's time to go to bed,’” he said.

A more recent complication, resulting from the liver's inability to remove ammonia from the bloodstream, has interfered with Bort's ability to speak and walk.

“It's little stuff like that, that you used to take for granted, that's so frustrating,” he said.

Still, he has hopes of returning to the courthouse once he has a new liver.

“I don't want to be the person sitting on the porch,” he said. “I want to work. I love my job at the Courthouse.”

Heisel said the PBLC has seven pending grievances against the Sheriff's Department regarding Albrecht's move to switch deputies from 12-hour to eight-hour shifts. Though touted as a move to save money as the county struggles with an ever tightening budget, Heisel claims the change has resulted in the county paying more overtime than ever before.

“I am confident that if you average out the overtime being paid, each deputy is earning 30 to 40 hours in overtime per month,” she said.

She also disputes the claim the move allowed the Sheriff's Department to put more officers on the road per shift. Other counties facing similar budget issues have responded by switching from eight-hour to 12-hour shifts, she said, to reduce costs and put more officers in the field.

“I've not been able to have a sincere conversation about the issue,” she said. “But if it was to eliminate overtime and put more officers on the road, it's failed.”

She said Macoupin County deputies are now working eight-hour shifts and filling in for shifts that are understaffed.

“They are running themselves into the ground,” she said. Because overly tired deputies may be required to drive from one end of the county to another to respond to emergencies “it's now becoming an issue of safety.”

Moreover, the union is handling an unfair labor practices grievance alleging some deputies were switched from 12-hour to eight-hour shifts in retaliation for their support of switching from the FOP to the PBLC for labor representation.

She said the union also is in the process of scheduling its first bargaining sessions to renegotiate a contract with the Sheriff's Department that expired at the end of August.

## ***Cancer common after liver transplantation***

[www.reuters.com](http://www.reuters.com)

NEW YORK (Reuters Health) - People who undergo liver transplantation, particularly children, are at increased risk for developing cancer, Finnish researchers report in the journal *Liver Transplantation*.

"On the basis of our data," Dr. Fredrik Aberg, from the Helsinki University Central Hospital, and co-authors note, "1 of 6 liver transplant patients is estimated to develop some form of cancer by 20 years after transplantation."

Although post-transplant cancer are a recognized problem, "more studies are needed to obtain reliable data on cancer risk patterns in an attempt to reach consensus on optimal monitoring of (immune-suppressing drugs), cancer surveillance programs, and strategies to minimize cancer risk," the authors maintain.

Their study included all 540 patients who received liver transplants at Aberg's center between 1982 and 2005, linked with the nationwide Finnish Cancer Registry. During follow-up, 39 cancers developed in 36 patients, which translates into a 2.59-fold increased risk relative to that seen in the general population.

Rates were higher among children younger than 17 years of age than among older patients. The cancers developed anywhere from 4 months to 14 years after the transplant operation.

Further analysis showed that only non-Hodgkin lymphoma, a cancer of the body's infection-fighting lymphatic system, and certain types of skin cancer were more common in liver transplant recipients than in the general population.

Risk factors for skin cancer were older age and the type of immune-suppressing drugs received, while those for non-Hodgkin lymphoma were male gender, young age, and the immediate post-transplant period.

Aberg's team, "This study points out the importance of cancer surveillance after liver transplantation as well as the need for innovative immunosuppression strategies associated with less cancer risk."

*SOURCE: Liver Transplantation, October 2008.*