

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

*Alan Franciscus  
Editor-in-Chief*

Week Ending: July 19, 2008

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July 13, 2008

### ***Hepatitis patients to reach settlement with drug companies***

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

FUKUOKA (Kyodo) A group of people who contracted hepatitis C through tainted pharmaceutical products will reach a settlement with drug manufacturer Mitsubishi Tanabe

Pharma Corp. and its subsidiary, possibly in August, one of the lawyers representing the patients in a damages suit said Sunday.

Yoshiaki Yamanishi, head of the secretariat for the lawyers' group representing patients in Osaka Prefecture, told reporters, "At the earliest, a basic agreement will be concluded in the second half of August."

Yamanishi made the remark after a meeting in Fukuoka of plaintiffs and their lawyers from various parts of the country.

"Mitsubishi Tanabe has said a proposal similar to a draft basic agreement presented by the plaintiffs on June 23 will be deliberated at a meeting of directors," he said.

At the meeting Sunday, the participants confirmed that in order to reach a settlement they will hold a meeting in which they hope to receive sincere apologies from executives of Mitsubishi Tanabe and subsidiary Benesis Corp., which is also named in the lawsuit along with Nihon Pharmaceutical Co.

In January, the plaintiffs reached a basic agreement with the state. In the same month, the government passed a special measures law to provide 12 million to 40 million yen in compensation to each patient. Since 2002, more than 900 people who contracted the disease through tainted blood products have joined the lawsuit.

**July 14, 2008**

### ***Hep B activists rejoice as China unblocks website***

<http://www.thestar.com>

Bill Schiller  
Asia Bureau

BEIJING—A website dedicated to helping China's nearly 100 million hepatitis B virus carriers is back up and running, after having been blocked inside the country for 43 days.

"This is good news – really good news," Chinese health activist Lu Jun told the *Toronto Star* yesterday. "Everyone in our community feels very happy about this."

The shutdown of Hbvhbv.com, which is managed by Lu, was the subject of a front-page Star article Friday. In the article Lu said he believed the shutdown was part of China's ever-tightening security in the lead-up to the Olympic Games.

A range of independent voices have in fact been silenced, shut down or placed under strict surveillance in recent months, especially those perceived to be potential threats to social order.

But Lu argued the shutdown of the hepatitis B website – which offers courage and public health counsel to carriers – was aggravating social tensions in China.

It was, he explained, stirring up anger against the Games, the government and the Communist party.

Lu waged an almost one-man campaign to have the site unblocked and had written to China's Ministry of Information.

Virus carriers face shocking job discrimination in China, and the website had become a vital forum for carriers to let off steam and seek mutual support.

Lu described the site, created in 2001, as "their only way to tell their stories, share their experiences (and) express their feelings."

Neither Lu nor staff at Beijing's Yirenping Centre, a counselling office for hepatitis B carriers, were notified by government that the site was to be unblocked.

"We think it was unblocked close to midnight on Friday," he said. "But it was after the Star's report, which we read online."

Some Star readers in China emailed the newspaper on the weekend suggesting the site could have been reactivated as early as 8 p.m. Friday in China – just hours after the article appeared.

Hepatitis B is the world's most common serious liver infection. The virus is transmitted through blood, unprotected sex or the use of unsterile needles as well as from infected mother to newborn.

### ***Community loses 'a great activist'***

<http://www.appeal-democrat.com>

During the month of June, our community lost a great activist. Although I didn't have the pleasure of working with her very often, I was aware of a lot of the work she did in our counties.

Sherri Zeigler educated our community on the issues surrounding Hepatitis C. She was responsible for educating hundreds of people every year on the dangers of Hepatitis C, informing people of the importance of prevention, and served as a resource for those stricken with this disease.

She was an outspoken, energetic, and honorable individual who definitely found her calling. Sherri was the face we saw and the voice we heard when the Hepatitis Task Force was doing the great work that they always do.

She touched thousands of lives in a positive way. The legacy she began at the Task Force will be missed but they will continue the excellent example that she set.

Thank you, Sherri, for your service to this community. Our counties were truly lucky to have you with us.

Jeff Olson  
Yuba City

## **Prepare, Protect, Prevent**

<http://include.nurse.com>

Robin Huiras

### *Boston RN Spreads Message After Acquiring Infections From Needle*

Karen Daley, RN, MPH, FAAN, thought nothing of it when she was stuck while discarding a needle after a routine blood draw at Boston's Brigham and Women's Hospital 10 years ago.

For the 23-year veteran of the ED, needlesticks seemed a part of the job. She had been stuck three times before with no lasting consequences. And she had no reason to think this time would be any different.

In fact, she likely would have ignored the injury altogether and returned to work if a fellow nurse had not urged her to report the incident.

"So I went to the fast track in the ED and the nurse practitioner recommended, based on the nature of the stick — in particular, because we didn't know the source patient, that I begin prophylaxis. Because I assessed my exposure risk as low and had seen other healthcare workers come in feeling pretty sick after starting a prophylactic regime, I deferred. Unfortunately."

If Daley had accepted the prophylactic treatment on that July day in 1998, she might not have developed a life-threatening infection — HIV. She also acquired hepatitis C.

"At the time of my injury, we didn't know a lot about how effective some HIV meds were in preventing infection following exposure," Daley says. "There wasn't the literature that now indicates that 85 percent to 90 percent of these infections could possibly be prevented without post-exposure prophylaxis."

"Part of my message is I never thought this would happen to me, and having the opportunity to do it again, I would have taken it."

Since that December day 10 years ago when colleagues confirmed her diagnosis, Daley has been working to put a face to needlestick injuries in an effort to educate healthcare professionals and highlight the prevalence of such occurrences.

During the past 10 years, Daley has fought the infections with different combinations of drug therapies, which caused weight loss, hair loss, fatigue, nausea, rashes, and myriad other side effects. Although she no longer needs to take medication to fight the more slowly progressing hepatitis C infection, she has developed a better tolerance to her HIV medications and has returned to a relatively active lifestyle.

Not only has Daley, who was president of the Massachusetts Nurses Association at the time of the incident, traveled to 23 states, Asia, and Europe to spread her message, but she's embarking upon a new project — a doctoral dissertation at Boston College — to advance the body of knowledge regarding nurses' experience of these injuries.

"My experience was relatively positive," she says. "I got lots of support when I was ready to be visible to my colleagues and the institution where I worked at the time of my injury. Based on what I hear from individuals as I speak around the country, I don't think that's the experience for every healthcare worker."

While there appears to be a vast range of experiences described by nurses who sustain needlestick injuries, the injuries themselves are commonplace. According to the Centers for Disease Control, approximately 384,325 needlestick injuries occur in U.S. hospitals each year. What's more, researchers at the International Healthcare Workers Safety Center estimate nearly 146,000 additional needlestick injuries occur annually at non-hospital sites (based on the number of needles used at the facilities) for a total of about 503,000 such injuries industry-wide each year.

The American Nurses Association this month announced the findings of the 2008 Study of Nurses' Views on Workplace Safety and Needlestick Injuries, an independent nationwide survey of more than 700 nurses. According to the research, nearly two-thirds (64%) of U.S. nurses say needlestick injuries and blood-borne infections remain major concerns.

Further, the IHWSC estimates that HIV is transmitted to between 18 and 35 healthcare workers every year and hepatitis C to between 59 and 1,180 people annually as a result of these injuries.

More staggering still is the fact that the majority of sticks are preventable.

"With quality safety devices, up to 85 percent of these injuries are preventable," Daley says, adding that if retractable needles had been used at her facility and the sharps disposal box had been emptied instead of overfilled with needles, her injury could have been avoided.

Thanks, in part, to her efforts to spread sharps prevention awareness, the government passed the Needlestick Safety and Prevention Act of 2000, requiring healthcare facilities to use safer medical devices where feasible.

"I had no choice. I couldn't sit at home with this. I had to do something," Daley says.

And she's hoping her latest endeavor will help those like herself and the nursing profession better understand the experiences of those injured by needles, she says, adding no studies have been conducted to describe the impact and meanings of this experience. Given that nurses account for more than half of needlestick injuries, it's vital to understand how they cope with the injury and what services they require to meet their needs.

"I have concerns about there being a potential gap in [meeting nurses' needs]. As we rush to provide care, we ignore the caregiver's needs and there may be some loss to the profession if nurses' needs are not met. [Giving] attention to the healthcare needs of nurses will, in the long run, allow the profession to better meet the needs of society."

*Robin Huiras is a freelance writer in Illinois.*

## **Cytheris Receives EUR 1.5 Million (\$2.3 Million) from OSEO for HCV Clinical Development Program**

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

*Highly Competitive Government Award for Paris Region Recognizes Potential of Interleukin-7 as an Immunotherapy*

PARIS — Cytheris SA, a clinical stage biopharmaceutical company focused on research and development of new therapies for immune modulation, today announced that OSEO, France's national agency for industrial innovation, has awarded the company with a no interest loan of EUR 1.5 million, or \$2.3 million, to support its ongoing clinical development program in hepatitis C (HCV).

The OSEO award will provide partial funding for the HCV clinical development program of the Company's lead product, **recombinant human Interleukin-7 (r-hIL-7)**, a critical growth factor for immune T-cell recovery and enhancement. Clinical trials conducted on more than 75 patients in Europe, the United States and Canada have demonstrated the potential of r-hIL-7 to expand and protect CD4+ and CD8+ T-cells. Cytheris is currently conducting multiple international clinical studies of IL-7 in HCV, HIV and cancer.

"These awards are highly competitive and we are delighted that OSEO has singled out Cytheris, not only because of the financial implications but also because the stringent criteria applied in selecting the small number of award winners bring added credibility to our innovative IL-7 investigative product and its potential therapeutic application," said Michel Morre, DVM, President and CEO of Cytheris. "OSEO funding previously played an instrumental role at the Company's foundation in the form of a now fully reimbursed loan to support the initial IL-7 studies which allowed us to reach the credibility needed to attract venture capital. This new OSEO support provided for our HCV study will partially cover the manufacturing, clinical studies and personnel costs associated with the program as well as its expansion to include additional clinical sites in Asia."

### **About OSEO**

Established by the French Government to support the growth and development of innovative small and medium enterprises (SMEs) throughout France, OSEO aids and funds SMEs at the riskiest phases of their development. Its subsidiary, OSEO Innovation provides aid for technology-driven research projects with genuine potential for commercialization. Support is provided in the form of loans to be reimbursed if a project is commercially successful.

### **About Cytheris - [www.cytheris.com](http://www.cytheris.com)**

Cytheris SA is a privately held clinical-stage biopharmaceutical company focused on research and development of new therapies for immune modulation. These drugs aim at reconstituting and enhancing the immune system of patients suffering from cancer, chronic viral or bacterial infections such as HCV and HIV, or lympho-depleting treatments such as chemotherapy, radiotherapy, bone marrow transplantation (BMT) and hematopoietic cell transplantation (HCT).

The company operates from its headquarters and laboratories in Issy-les-Moulineaux, a suburb of Paris, and its U.S. subsidiary in Rockville, Maryland.

Cytheris French/International media inquiries Andrew Lloyd & Associates: Andrew Lloyd ([allo@ala.com](mailto:allo@ala.com)), Juliette dos Santos ([juliette@ala.com](mailto:juliette@ala.com)) Tel: +33 1 5654 0700

**July 16, 2008**

## ***New Model Allows Testing of Hepatitis C Treatments***

<http://news.yahoo.com>

WEDNESDAY, July 16 (HealthDay News) -- In a feat that should help researchers more effectively evaluate new treatments for hepatitis C, investigators report that they have developed the first tissue culture of regular human liver cells that can imitate infections with the hepatitis C virus (HCV).

"This is the first efficient and consistent model system for HCV to be developed," Martina Buck, assistant professor of medicine at the University of California, San Diego, School of Medicine, who developed the culture, said in a university news release. "There is a need for new treatments, and for development of a possible vaccine for HCV. Now we have a model system to support work by investigators in this area."

Some 170 million people worldwide are infected with hepatitis C, which affects the liver. In the United States alone, some 10,000 people die from cirrhosis of the liver, and thousands more die from liver cancer associated with infection.

The virus is usually transmitted by sharing intravenous drug needles and through sexual contact.

Right now, there is no animal model to test different therapies, according to background information in a paper published in the July 16 issue of *PLoS ONE*.

As of now, only one treatment for hepatitis C exists, Peg-interferon alpha, a drug combination that has a response rate of about 50 percent in people infected with HCV but only about 20 percent in individuals with cirrhosis of the liver.

The therapy can also cause severe flu-like symptoms.

Researchers have so far been hampered in their efforts to understand HCV, because it hasn't been possible to infect normal human liver cells in a laboratory setting.

The new culture allows scientists to directly infect cells with virus from the blood of HCV-infected patients.

## ***Surgery may be option for advanced liver cancer***

<http://www.reuters.com>

NEW YORK (Reuters Health) - Surgical removal of liver cancer may be a useful treatment and should at least be considered in patients with multiple tumors or vascular complications, according to a report in the journal *Gastroenterology*.

Current guidelines that recommend surgery only for patients with a single tumor and no vascular complications may be too strict, Dr. Norihiro Kokudo from University of Tokyo, told Reuters Health.

Kokudo and colleagues assessed the therapeutic value of surgery for liver cancers with multiple tumors and vein complications and reevaluated the treatment guidelines for liver cancer, which have been based on data obtained mainly in Western countries.

Although long-term overall survival was lower in patients with multiple tumors than in patients with single tumors, the authors report, patients with multiple tumors were still able to achieve 5-year survival rates of up to 58 percent.

Long-term overall survival was also poorer in patients with vein complications, but 5-year rates as high as 56 percent were seen, the report indicates.

Generally, it is thought that a curative treatment, such as surgery, may be considered if the 5-year survival rate exceeds 50 percent. These findings therefore support the potential use of surgery for patients with multiple tumors or vein complications.

The best results were seen in patients with relatively normal liver function, known as Child-Pugh class A. Kokudo said that patients with worse liver function (class B) may not be good candidates for surgery, but depending on tumor characteristics, such as the location, surgery may still be a valuable treatment.

*SOURCE: Gastroenterology, June 2008.*

## ***BioAlliance Pharma Suspends the Phase II/III Trial of Doxorubicin Transdrug in Primary Liver Cancer***

<http://pharmalive.com>

PARIS, July 16, 2008 - BioAlliance Pharma SA (Euronext Paris -BIO), the specialty pharmaceutical company focused on the treatment of opportunistic infections in cancer and HIV, announced today the suspension of its Phase II trial of **doxorubicin Transdrug** in primary liver cancer. The company is following advice (as set out in the study schedule) provided by the Drug Safety Monitoring Board and the Steering Committee, which have been continuously monitoring the trial's progress. On the basis of the initial data, the two committees observed a clinical benefit but also more frequent and more severe pulmonary adverse events than expected and have thus recommended suspension of the trial, given the incidence of this type of effect.

This type of acute pulmonary damage was observed in Phase I/II trial at a dose of 35mg/m<sup>2</sup> (the maximum tolerated dose) but had not been observed at 30mg/m<sup>2</sup>, the dose chosen for repeated administrations in the next development phase.

In this Phase II trial, doxorubicin Transdrug was being compared with the current standard of care (a control group undergoing Trans-Arterial Chemo-Embolization).

In terms of the criteria for assessing the efficacy and safety of repeated intra-arterial hepatic injection of doxorubicin Transdrug, the efficacy endpoint was based on progression-free survival after 3 months of treatment.

"Non-operable primary liver cancer in cirrhotic patients has a very poor prognosis. There are few effective treatments, and it is therefore important to evaluate the benefit/risk ratio of therapeutic innovations," stated Dominique Costantini, BioAlliance Pharma's co-founder, President and CEO. "We scheduled Drug Safety Monitoring Board and Steering Committee meetings into the trial's timeline and we have been following their recommendations".

Our product portfolio is based on independent innovations, and each has its own risks. This allows us to redirect our focus so if this trial has to be suspended permanently, we shall bring another compound into the clinical phase," added Dominique Costantini.

### **About BioAlliance Pharma**

BioAlliance Pharma SA is a specialty pharmaceutical company focused on the treatment of opportunistic infections in cancer and HIV. The company develops and commercializes innovative products which address resistance issues. The company has launched its first portfolio product (Loramyc) in France and already received European Marketing Authorizations in UK, Germany, Belgium, Denmark and Luxemburg. The compound has completed the pivotal Phase III clinical development in oropharyngeal candidiasis in the USA. In addition, two other innovative products are currently in Phase III clinical trials: acyclovir Lauriad in oral herpes (based on the same Lauriad muco-adhesive technology as Loramyc, which enables targeted release at the disease site) and doxorubicin Transdrug in primary liver cancer (based on the Transdrug nanoparticle technology, designed specifically for intracellular targeting of resistant cells). The company is also developing a new therapeutic entities program focused on the oncology and infectious disease markets.

In 2007, the company has established strategic alliances for commercializing Loramyc in Europe (with JV SpeBio) and in the USA with Par Pharmaceutical. In March 2008, BioAlliance Pharma signed a partnership agreement with Handok Pharmaceuticals for commercializing Loramyc in Korea, Taiwan, Singapore and Malaysia and with Novamed Pharmaceuticals in June 2008 for commercialization of Loramyc(TM) in China. In May 2008, the company expanded its product portfolio via acquisition of the European commercial rights to ondansetron Oral Spray (OS) from NovaDel Pharma Inc. (Amex: NVD).

For more information, visit BioAlliance Pharma's website at [www.bioalliancepharma.com](http://www.bioalliancepharma.com).

### ***Demographic Variations Seen in Liver Cancer Incidence in US***

<http://www.reutershealth.com>

NEW YORK (Reuters Health) Jul 09 - The incidence of hepatocellular carcinoma in the US differs significantly by sex, ethnicity, and age at diagnosis, according to results of a study published in the June issue of the *American Journal of Medicine*.

"The increasing incidence of hepatocellular carcinoma coupled with this cancer's high mortality is a public health problem," write Dr. Robert Wong, of the University of California, San Francisco, and colleagues. "Current clinical guidelines recommend initiating hepatocellular carcinoma screening in some high-risk groups, but little data are available in the United States regarding how cancer incidence may differ by age and race/ethnicity."

The team used data from the Surveillance, Epidemiology, and End Results program, a population-based cancer registry, to examine the age-specific, sex-specific, and race-specific variability of hepatocellular carcinoma incidence from 1992 to 2004.

A total of 18,442 cases of hepatocellular carcinoma were identified. When males and females were combined, the team found that Asians had nearly twice the incidence rate of white Hispanics (11.0 versus 6.8 per 100,000/y;  $p < 0.0001$ ) and more than four times that of Caucasians (11.0 versus 2.6 per 100,000/y;  $p < 0.0001$ ).

Males had a doubling of cancer rates every 10 years from 30 to 50 years of age, according to the authors. "Females reached male-comparable rates of cancer 10 to 15 years later, and they peaked at significantly lower values for all race/ethnic groups," the team found.

"The possibility that groups with similar identifiable risk factors can present with significantly different disease risk suggests that, if screening is effective, an individualized approach may more efficiently identify treatable tumors than more general guidelines, while minimizing interventions on patients with relatively lower risks of progressing to cancer," Dr. Wong's team concludes.

They add, "More studies are needed to determine disease-specific variations in cancer risks (e.g., hepatitis B and C) and whether incorporating the variations observed into surveillance protocols is clinically efficacious."

*Am J Med 2008-121:525-531.*

## ***Bevacizumab Shows Significant Activity in Liver Cancer***

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

By Martha Kerr

NEW YORK (Reuters Health) Jul 09 - **Bevacizumab**, a monoclonal antibody targeting vascular endothelial growth factor (VEGF), may be an option in nonmetastatic unresectable hepatocellular carcinoma (HCC), according to the results of a phase 2 study reported in the July issue of the *Journal of Clinical Oncology*.

The multicenter study, led by Dr. Abby B. Siegel of Columbia University College of Physicians and Surgeons in New York, involved 46 patients with HCC and compensated liver disease. Twelve patients received bevacizumab 5 mg/kg and 34 patients received 10 mg/kg every two weeks until disease progression or treatment-limiting toxicity occurred.

Six patients (13%) had objective responses, and 65% of patients were progression-free at 6 months.

Overall survival was 53% at 1 year, 28% at 2 years and 23% at 3 years.

Grade 3-4 adverse events included hypertension in 15% and thrombosis in 6%. Grade 3 or higher hemorrhage occurred in 11%, including one fatal variceal bleed.

"After we amended the protocol to require endoscopy for at-risk patients, we had no further variceal bleeds," Dr. Siegel noted during an interview with Reuters Health. "We subsequently had two more serious bleeds (4%), which is within the same range as bleeding rates seen in trials of bevacizumab in lung cancer."

Her group is planning several trials using bevacizumab "with other targeted and chemotherapeutic agents in hepatocellular carcinoma both at Columbia and across the country," Dr. Siegel noted.

"Several studies are evaluating whether moving bevacizumab 'up front' to the adjuvant setting may be helpful," she added. "This is a mechanistic question, because nobody knows whether bevacizumab will be able to help eradicate minimal residual disease, or whether it works best when there is existing measurable disease."

*J Clin Oncol 2008;26:2992-2998.*

## ***Biliary Complications More Common in Living Donors of Right Liver Lobe Grafts***

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

NEW YORK (Reuters Health) Jul 04 - Living liver donors are significantly more likely to experience biliary complications when donating a right lobe than a left lobe, results of a study from Japan suggest. The researchers also found that endoscopic management of these complications is usually effective when conservative therapy fails.

"With the increasing number of living donor liver transplantations, biliary complications in donors have emerged as a major postoperative problem," the team points out in the June issue of the *American Journal of Gastroenterology*.

Dr. Seiji Shio and colleagues from the departments of gastroenterology, hepatology and surgery at Kyoto University Graduate School of Medicine analyzed biliary complications in 731 consecutive patients who donated liver grafts (434 right-lobe and 297 left-lobe grafts) for transplantation.

Overall, postoperative biliary complications occurred in 55 donors, or 7.5%. Initially, 48 of these 55 donors had biliary leakage and 7 had biliary stricture. Subsequently, 5 of the 48 donors with leakage developed biliary stricture.

According to the investigators, the rates of biliary leakage and overall biliary complications were significantly higher ( $p < 0.01$ ) among right-lobe donors (9.9% and 11.1%, respectively) than among left-lobe donors (1.7% and 2.4%).

The incidence of biliary stricture was also higher among right-lobe donors than among left-lobe donors (2.1% vs 1.0%), but the difference did not reach statistical significance.

"Anatomic variations in the biliary tract appear to be one of the most important factors contributing to the higher incidence of biliary leakage among right-lobe donors," Dr. Shio and colleagues note.

Among the 55 donors with biliary complications, 24 were successfully treated with conservative therapy and 1 was converted to surgical repair due to ileus, the investigators report.

Eighty percent of the donors whose biliary complications could not be treated by conservative therapy were successfully treated with endoscopic retrograde cholangiography, while the remaining 20% underwent surgery due to difficulties with cannulation, excessive biliary leakage, or complete biliary obstruction.

Endoscopic treatment of biliary complications in living liver donors is effective, Dr. Shio and colleagues conclude, "and should be used as the first-line treatment for such complications."

*Am J Gastroenterol 2008;103:1393-1398.*

## ***Purer, Less Costly Interferon for Hepatitis C and B Treatment***

<http://www.vaccinex.com>

Written by Vaccine Rx Staff

Drug development company PharmaEssentia Corp. today announced that new PK/PD data on P1101, its third-generation PEG-interferon-alpha drug candidate for hepatitis B and C, showed the drug is particularly long-lasting compared to the two other pegylated-interferon drugs currently on the market. This indicates that PharmaEssentia's drug may only need to be injected once every two or more weeks by the patient, compared to the usual once-a-week administration.

Reducing dosage frequency is considered desirable for minimizing side effects and increasing the efficacy; and is more convenient for the patient as such biopharmaceutical drugs must usually be administered by injection.

Additionally, the modified structure of PharmaEssentia's PEG-INF-alpha makes for a purer drug, leading to a simpler manufacturing process and better quality control over the end product, particularly when produced at higher doses. P1101 has only a predominant single positional isomer connecting the PEG molecule on the protein, compared with 8 to 14 isomers found in the two other pegylated-interferon drugs, respectively.

Less frequent dosage should also mean a lower end cost and better compliance for the patient.

Assuming that upcoming clinical trails are all completed successfully, Dr. KC Lin, founder and CEO of PharmaEssentia, sees the drug gaining rapid acceptance and market share upon launch.

"Our drug will be purer, easier to manufacture, and more importantly, a more convenient and cheaper interferon option for doctors and patients. It's set to transform the whole picture of HCV/HBV treatment," explained Lin.

**July 17, 2008**

## ***Hepatitis C: Living with the Disease***

<http://www.associatedcontent.com/article/884575>

By Rose R.

*Natalie Cole is the Next Victim of This Silent Killer*

It was announced across the country today that singer and daughter of the late Nat King Cole, Natalie Cole had been diagnosed with Hepatitis C. Her drug use is suspected for causing the disease. Ms. Cole told reporters that even though she had conquered her past, she was still going to the effects of bad choices years ago. She has started a regime of treatment that has been prescribed by her physician.

It has been called a 'silent killer' because you can go for years with no symptoms. It is also a silent killer because it has not been diagnosed and dealt with in an effective way. Nine out of ten of us who have hep C simply didn't know we had it.

I had Hepatitis C for 20 years before I knew it. Through a blood test to give blood, I was diagnosed. The initial reaction to getting Hepatitis C is total shock. How could you have something like this and not know it. Because the symptoms for years are very mild and can mask themselves as exhaustion and stomach issues, you don't feel something is wrong with you.

I got Hepatitis C from the birth of my oldest daughter. This happened back in 1980. Back then, so little was known about the different strains of Hep C, the doctors were not able to diagnose it as such. I got the initial jaundice, vomiting and fever. The doctors told me it was Hepatitis, but it was Hepatitis A. No big deal they said.

I lay on the bed with a newborn baby for 6 weeks with neighbors and my husband nursing me back to health from both delivery of a child and the Hepatitis. As I got better, my doctor never checked me for it again. Because Hepatitis A is not a long term health issue, I never thought about it again. That is not until I started having episodes of extreme tiredness, always fighting pain on my right side. Feeling swollen, vomiting and more.

I went to the doctor and through blood tests I was diagnosed with a much more aggressive Hepatitis C. After taking the news for its worst and feeling like I had been issued a death sentence, I pulled myself back together and got lots of information.

My doctor did tests to see how far along I had progressed in terms of damage to my liver and potential for cirrhosis or cancer. I went in for a liver biopsy and was relieved to find out that even though I had carried it for many years; I had not sustained major damage. The day to day symptoms were what really drained both attitude and physical strength.

Through all of the tests it was determined that I would benefit from Pegasus treatments. Pegasus treatments are a combination therapy that is supposed to attack the Hepatitis C and put it into remission.

The side effects of this I was told is lactic acidosis (your cells die) tiredness, nausea/vomiting, abdominal pain, shortness of breath...The doctor told me about fever like symptoms such as chills, muscle pain, headaches... Insomnia, difficulties in concentration and clear thinking can also be seen in some people.

I was even more apprehensive at that point than I was when they told me I had this thing. It appeared I was going to be even more sick with medicine than I was without it. I was not happy.

At the time I lived in Florida. Before I could complete the workup and the approval process to start Pegasus treatments, my husband was transferred to Colorado. We changed insurance so the process had to be started all over again. I spent the next 9 months getting tests, making preparations etc. Due to other health issues, I started losing a lot of blood. That dominated my life for the next 12 months.

After 3 blood transfusions and surgery, I began again to get tested and start the process for the treatments. During the next 6 months and many blood tests, my doctor called me in for a consultation. She told me I was Hepatitis C free.

I fired her and got a new doctor. The first set of tests showed that my Hepatitis C was non existent. I had a biopsy to see what it would say. It said I still had very minimal damage from the Hep C but there was no sign I still had it.

As amazing as that was, there are over 400 million people in this country who have it. It is not necessarily a death sentence. It is however necessary to seek out medical advice as soon as you can. If you are feeling run down and not yourself, have been vomiting or pain in your right quadrant of your body, get checked out. Blood tests are simple.

For the most part anyone who has tried intravenous drugs has run the risk of Hepatitis C and should be tested. Unsafe sex practices can expose you to Hepatitis C. People who have experimented in either of these know they have taken risks. It is better to get checked in order to prevent major damage.

Hepatitis C can lead to cirrhosis of the liver and liver cancer. If you drink alcohol, you put yourself at risk even more.

Once diagnosed with this disease there are many, many resources to answer questions and offer support, as well as provide valuable information to help you recover. I was very lucky. The doctor said 1 person in 8000 will get well from Hepatitis C without treatment.

Check the links on this site if you have been diagnosed with Hepatitis.

### **More resources**

[www.cdc.gov](http://www.cdc.gov)

## ***EpiCept and GNI join hands to develop hepatitis drug in Asia***

<http://www.pharmaceutical-business-review.com>

By Staff Writer

GNI and EpiCept have reached an agreement to develop a new therapeutic drug, EP1013, in Asia, Australia, and New Zealand, for late-stage viral infection-induced hepatitis.

Under the agreement, EpiCept will retain the rights in the rest of the world. GNI's wholly owned subsidiary, Shanghai Genomics, will start preparation for pre-investigational new drug (IND) application and clinical development in China immediately.

In return for granting a license to GNI to develop EP1013, EpiCept earned an upfront license fee and will be eligible to earn milestone payments and royalties on commercial sales. GNI intends to complete toxicology and pharmacokinetic studies to prepare for an IND filing with the Chinese SFDA as soon as possible.

Jack Talley, president and CEO of EpiCept, said: "We are pleased to establish this collaboration to accelerate the development of EP1013 for a therapeutic area which is outside of our core focus areas in oncology and pain management. Caspase inhibitors may provide a new therapeutic modality for the treatment of degenerative diseases that involve apoptotic cell death."