

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Editor-in-Chief*

**Week Ending: July 31<sup>st</sup>, 2004**

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**July 26<sup>th</sup>, 2004**

### ***Possible Role for Vitamin K2 in the Prevention of Hepatocellular Carcinoma in Women with Viral Cirrhosis***

*Source: [www.gastrohep.com](http://www.gastrohep.com)*

The role of vitamin K2 in the development of hepatocellular carcinoma in women with viral cirrhosis has been explored in a paper published in the July 21st issue of the *Journal of the American Medical Association*.

The role of vitamin K2, or menaquinone, in controlling cell growth has been identified in previous studies.

Japanese scientists were therefore interested to discover if vitamin K2 has preventative effects on the development of hepatocellular carcinoma in women with viral cirrhosis of the liver.

Dr Daiki Habu and colleagues from Osaka City University, Osaka, Japan studied 40 women diagnosed with viral liver cirrhosis who were admitted to a university hospital between 1996 and 1998.



The women were randomly assigned to either the treatment group, who received 45 mg/d of vitamin K2 (n = 21), or the control group, who did not receive the vitamin treatment.

Both groups received symptomatic therapy to treat ascites, if necessary, and dietary advice.

The scientists originally set out to assess the long-term effects of vitamin K2 on bone loss in women with viral liver cirrhosis.

However, since study participants also satisfied criteria required for examination of the effects of such treatment on the development of hepatocellular carcinoma, they focused their attention on this.

Hepatocellular carcinoma was detected in 2 of the 21 women given vitamin K2 and 9 of the 19 women in the control group.

The cumulative proportion of patients with hepatocellular carcinoma was smaller in the treatment group, while on univariate analysis, the risk ratio for the development of hepatocellular carcinoma in the treatment group compared with the control group was 0.20.

On multivariate analysis with adjustment for age, alanine aminotransferase activity, serum albumin, total bilirubin, platelet count, -fetoprotein, and history of treatment with interferon alfa, the risk ratio for the development of hepatocellular carcinoma in patients given vitamin K2 was 0.13.

The researchers therefore conclude that there is a possible role for vitamin K2 in the prevention of hepatocellular carcinoma in women with viral cirrhosis.

*JAMA 2004; 292 (3): 358-361*

**July 28<sup>th</sup>, 2004**

## ***Hepatitis C and Early Acute Rejection Following Liver Transplantation***

*Source: www.gastrohep.com*

HCV etiology is strongly associated with early acute rejection following liver transplantation, find doctors in the August issue of *Liver Transplantation*.

Diagnosis and treatment of early acute rejection likely affect the course of recurrent hepatitis C virus (HCV) following liver transplantation.

In this study, doctors from San Francisco, California, evaluated a cohort of liver transplantation recipients to re-examine risk factors for early acute rejection.

The team hypothesized that HCV etiology may represent a significant risk factor for early acute rejection.

They retrospectively reviewed the records of 285 adults undergoing primary liver transplantation for cirrhosis between 1999 and 2002.



Overall incidence of rejection = 41%. -- *Liver Transplantation*

The doctors found that HCV cirrhosis was the etiology for 51% of all liver transplantation recipients.

They also found that there were 135 episodes of early acute rejection in 117 recipients; an overall incidence of 41%.

Patient groups with HCV and cholestatic/autoimmune disease had the greatest incidence of rejection (49%).

Univariate analysis identified recipient gender, ethnicity, etiology, year, and posttransplant immunosuppression levels were risk factors for early acute rejection.

However, HCV etiology and female gender remained robust risk factors in multivariate analysis.

Interferon-based therapy did not impact the incidence or timing of early acute rejection.

Dr Ryan McTaggart and colleagues concluded, "HCV etiology is strongly associated with early acute rejection".

"HCV allograft reinfection may create an immunologic environment predisposed to early acute rejection".

"Alternatively, the association of HCV and early acute rejection may result from an increased frequency of allograft biopsy and may be further exacerbated by inability to accurately diagnose early acute rejection in the setting of recurrent HCV".

*Liver Transpl 2004; 10(8): 975-85*

**July 28<sup>th</sup>, 2004**

## ***National Institutes of Health Researchers Identify Better Hepatitis C Treatment for People with HIV***

*Source: National Institutes of Research*

### *Researchers Identify Better Hepatitis C Treatment for People with HIV*

The preferred treatment for hepatitis C, peg-interferon and ribavirin, is safe for people who are also infected with HIV, according to a new study in the July 29 issue of *The New England Journal of Medicine*. Moreover, this treatment proved superior for the treatment of hepatitis C virus (HCV) in HIV-coinfected persons when compared with the previously accepted treatment, standard interferon and ribavirin.

The study compared the effectiveness of two forms of interferon: a once-weekly dose of peg-interferon and standard interferon taken three times weekly. Peg-interferon with ribavirin is currently the approved treatment for hepatitis C in persons without HIV. Prior to this study,



limited data were available on the benefit and safety of peg-interferon and ribavirin in HIV-infected people.

The study was funded by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Center for Research Resources (NCRR), both parts of the National Institutes of Health (NIH). NIAID's Adult AIDS Clinical Trials Group conducted the study at 21 research centers in the United States.

“We are pleased to see such a clear and definitive result from this study,” says NIAID Director Anthony S. Fauci, M.D. “Just a decade ago treatment of HCV in persons infected with HIV was not a priority because they died from AIDS before developing serious complications of hepatitis C infection. As new anti-HIV drug treatments extend the lives of HIV-positive individuals, studies like this one provide essential guidance on treating other serious health problems affecting people living with HIV.”

HCV is primarily spread through infected blood. Most people with the virus have no signs of illness, but in some the infection progresses to chronic liver disease, liver failure or liver cancer. The disease progresses more rapidly in people who have HIV.

The Centers for Disease Control and Prevention (CDC) estimate that HCV infects about 25,000 Americans annually and is responsible for about 8,000 to 10,000 deaths per year. About 3.9 million Americans have been infected with HCV, 2.7 million of whom are chronically infected, according to the CDC. It is also estimated that of the 1 million HIV-infected Americans, about 300,000 are also infected with HCV.

“We carefully monitored the study volunteers for side effects. Most tolerated the treatments well, and relatively few discontinued therapy prematurely. We were also encouraged that HIV infection remained under control during the study,” says Raymond T. Chung, M.D., lead investigator and director of the Center for Liver Disorders in the Gastrointestinal Unit at Massachusetts General Hospital.

The 133 HIV-positive study volunteers were randomly assigned to take peg-interferon or interferon for 48 weeks. All study volunteers also took ribavirin, an antiviral drug that is also part of standard therapy for hepatitis C. Study volunteers who completed the treatments—16 withdrew early for various reasons—were followed for 24 more weeks to evaluate long term treatment success.

In the group that took peg-interferon, 27 percent of patients had no detectable HCV in their blood 24 weeks after completing treatment (sustained response). In contrast, of those who took interferon, only 12 percent had a sustained response. Importantly, more than one third of those volunteers who failed to clear HCV appeared to experience improvement in their liver biopsies, suggesting the treatment was beneficial in this group as well. Researchers also found that the volunteers whose HCV levels failed to fall substantially within the first 12 weeks never experienced a sustained response.

Roche Laboratories provided study medications and participated in the protocol team.

NCRR supported this research through its General Clinical Research Center Program with grants to University of Rochester, NY; University of North Carolina, Chapel Hill; and New York



University. NCCR provides NIH-supported investigators with access to specialized basic and clinical research facilities, technologies, instrumentation, biomaterials, animal models, genetic stocks and more.

**Reference:**

R.T. Chung et al. A randomized controlled trial of PEG-interferon alfa-2a plus ribavirin vs. interferon alfa-2a plus ribavirin for chronic hepatitis C virus infection in HIV-co-infected persons: the U.S. AIDS Clinical Trials Group A5071 study team. *The New England Journal of Medicine* 351(5):451-459 (2004).

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NIAID is a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

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## ***Idun Pharmaceuticals Initiates Phase 2 Clinical Study of IDN-6556 in Hepatitis C Virus***

*Source: PRNewswire*

SAN DIEGO,-- Idun Pharmaceuticals, Inc. today announced that it has initiated a Phase 2 clinical study of IDN-6556 in patients infected with hepatitis C virus (HCV). The dose-response study will evaluate whether IDN-6556 can decrease the liver damage that occurs from hepatitis, an inflammation of the liver, which can be caused by HCV infection. Participants in this trial will have previously failed to respond to existing drugs for HCV and will receive one of several doses of IDN-6556, or placebo, given orally as a monotherapy for 3 months. This study will be conducted at fifteen sites in the U.S. and is expected to enroll up to 200 patients.

"The initiation of this Phase 2 clinical study of IDN-6556 is an important milestone in the development of this exciting new candidate for the treatment of diseases of the liver," said David Shapiro, M.D., Idun's Chief Medical Officer. "We believe that IDN-6556 has considerable potential to treat not only HCV but several other liver diseases based on the encouraging data from the previous clinical experiences. These data have been presented at a number of recent medical meetings including the American Association for the Study of Liver Disease, the European Association for the Study of the Liver and Digestive Disease Week. The current Phase 2 trial seeks to repeat and expand on the results observed in the previous trial and should provide important additional information about safety, dosage and markers of disease progression."

Additional information about participating in this clinical trial can be obtained at the Idun web site at [www.idun.com](http://www.idun.com).

### **IDN-6556**

IDN-6556 is a first-in-class, small-molecule pan-caspase inhibitor being developed as a broad liver protectant. IDN-6556 efficiently targets the liver and has been shown to be highly effective



in a variety of preclinical models of liver disease demonstrating both anti-inflammatory and anti-fibrotic activity. In previous human clinical trials, IDN-6556 was shown to be well tolerated following oral administration for up to two weeks across a wide range of doses. IDN-6556 significantly decreased elevated aminotransferase liver enzymes, a routine measure of liver damage, within days after administration.

### **Hepatitis C**

The number of individuals with chronic hepatitis C infection is estimated at 2.7 million in the U.S. and up to 10 million patients worldwide. Principally due to the side effect profile and the expensive cost of current therapies, only about 13% of the chronically infected in the United States and roughly 7% of the chronically infected in other developed countries have been treated. Over 30% of patients with chronic hepatitis C will likely develop cirrhosis of the liver and ultimately require a liver transplant.

### **Idun**

Idun Pharmaceuticals, Inc. is a privately-held biopharmaceutical company dedicated to the discovery and development of novel therapeutics in the areas of liver disease, inflammation, and cancer. Idun's lead product candidate, IDN-6556, is in clinical studies for both liver transplantation and in patients infected with hepatitis C virus. The company has a number of product candidates in advanced preclinical development for inflammation and cancer. Idun has an extensive patent portfolio comprised of 146 issued patents worldwide. Idun's corporate headquarters and research and development facility is located in San Diego, California. For more information please visit the company's web site at [www.idun.com](http://www.idun.com).

Some of the statements in this press release are forward-looking statements and do not guarantee future performance and involve risks and uncertainties. Actual results may differ substantially from the results that the forward-looking statements suggest for various reasons. These forward-looking statements are made only as of the date of this press release.

*Source: Idun Pharmaceuticals, Inc.*

**July 29<sup>th</sup>, 2004**

### **Viragen Granted U.S. Patent for Manufacture of Multiferon(TM)**

*Source: PRNewswire*

PLANTATION, Fla.—Viragen, Inc.(Amex: VRA) and Viragen International, Inc. (OTC Bulletin Board: VGNI) today announced they have been granted U.S. Patent 6,743,624 from the United States Patent & Trademark Office for a process relating to the manufacture of Multiferon™, a natural human alpha interferon drug derived from human white blood cells.

The issued patent titled, “Process For Continuous Purification And Concentration Of Leukocytes From Blood,” relates to a novel process used to concentrate leukocytes (human white blood cells) during the production of Multiferon, which results in an enhanced yield of interferon from the cell preparation.

“Obtaining patent protection for this key aspect of our manufacturing technology represents one step in providing Viragen with an important competitive advantage as we continue our evaluation of ways to bring Multiferon to the United States,” stated Viragen’s Executive Vice



President, Mr. Mel Rothberg. “We continue to review the multiple options available to us for this part of our Multiferon strategy.”

### **About Alpha Interferon:**

The majority of alpha interferons that are marketed for the treatment of a broad range of viral and malignant diseases are single-subtype recombinant interferons. Therapy resistance is not unusual with recombinant interferons with a significant percentage of patients failing to respond to standard therapy. In some instances, recombinant interferon is rejected by the patient’s immune system, possibly the result of the formation of neutralizing antibodies which may lead to a loss of clinical efficacy. Also, many patients cannot tolerate the adverse side effects sometimes associated with recombinant therapy.

### **About Multiferon™:**

Multiferon is a highly purified, multi-subtype, natural human alpha interferon derived from human white blood cells and is approved in Sweden for the second-line treatment of any and all diseases in which patients show an initial response to recombinant (synthetic) alpha interferon followed by treatment failure, probably due to the formation of neutralizing antibodies.

Multiferon is also approved for sale in the following countries for the treatment of a range of viral and malignant diseases: Czech Republic, Egypt, Hong Kong, Indonesia, Mexico, Myanmar, South Africa and Thailand. Work is ongoing to expand the approved indications in these countries. Regulatory approval processes are also underway in a number of other South American, Middle East and Far East territories.

Multiferon is not approved for sale in the United States, and Viragen is required to file an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA) to be allowed to test the drug in U.S. human studies.

To view a print ad for Multiferon, please visit: <http://www.Viragen.com/multiferonad.htm>

### **About Viragen, Inc.:**

Viragen is a biotechnology company specializing in the research, development and commercialization of natural and recombinant protein-based drugs designed to treat a broad range of viral and malignant diseases. These protein-based drugs include natural human alpha interferon, monoclonal antibodies and a peptide drug. Viragen’s strategy also includes the development of Avian Transgenic Technology as a biomanufacturing platform for the large-scale, cost-effective production of therapeutic proteins.

Viragen is publicly traded on the American Stock Exchange (VRA). Viragen’s majority owned subsidiary, Viragen International, Inc., is publicly traded on the Over-The-Counter Bulletin Board (VGNI). Viragen’s key partners and licensors include: Roslin Institute, Memorial Sloan-Kettering Cancer Center, Cancer Research UK, University of Nottingham (U.K.), University of Miami, America’s Blood Centers and the German Red Cross.

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

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The foregoing press announcement contains forward-looking statements that can be identified by such terminology such as “expect,” “potential,” “suggests,” “may,” “will,” “should,” “could” or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management’s expectations regarding future research, development and/or commercial results could be affected by, among other things, uncertainties relating to clinical trials and product development; availability of future financing; unexpected regulatory delays or government regulation generally; the Company’s ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general. Forward-looking statements speak only as to the date they are made. The Company does not undertake to update forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made.

*SOURCE Viragen, Inc.*

## **NEW - Hepatitis C Disinfectant Just Introduced in the Salon Industry, Could Mean the End of O’L BLUE!**

*Source: [www.prweb.com](http://www.prweb.com)*

SaniGuard an emerging leader in infection control products has introduced a complete line of sanitization products for the beauty and barber industry's including SaniGuard PRO™ the Industry’s First Hospital Grade Disinfectant with a Hepatitis C Efficacy Claim and 4 patent pending color choices.

For salon and spa owners, providing services to their clients in clean and safe surroundings has to be their number one priority. Until now the choices have been limited with no real advances with sanitization in the beauty & barber industry. To help achieve a healthy environment, SaniGuard®, an emerging leader in the medical and health field, has introduced a new cutting edge professional line of salon sanitization products, SaniGuard Professional Salon Products.

The SaniGuard Professional Salon Products line encompasses seven products with their first product release and includes many firsts in the salon and spa industry, such as the first Hepatitis C efficacy claim and patent-pending colored disinfectants for salon tools and implements.

### **The SaniGuard Professional Salon Products line includes:**

- SaniGuard PRO™ Concentrated Hospital Grade Disinfectant - The beauty and barber industry’s first EPA-registered hospital grade disinfectant with a Hepatitis C efficacy claim. SaniGuard PRO comes in four patent-pending colors (green, purple, red & yellow) and is virucidal, fungicidal, bactericidal and has been tested on and proven effective against TB, HIV 1 & 2, Hepatitis B & C, Herpes 1 & 2, Staph, Strep & over 50 other leading infection concerns including MSRA strains It also does not contain dangerous phenols like other TB approved products in the beauty industry.

- SaniGuard Barrier Skin Cream™ - The most advanced barrier skin cream introduced to date. When applied it dries quickly without any sticky residue and will provides temporary protection for 3-4 hours repelling everything from chemicals and dyes to perm solutions and water. In many applications it is making latex or vinyl gloves a thing of the past.



- SaniGuard Dry Sanitizing Surface Spray™ - The world's first dry on contact spray sanitizer and deodorizer. Due to its dry on contact properties, it safely sanitizes surfaces that ordinary wet products damage. From electronics to rubber to fabrics and even paper, without damage!

- SaniGuard Total Release Fogger™ - The World's first disposable room fogger. It enables the user to quickly sanitize entire rooms in just minutes with the same "kill on contact" power of the conventional SaniGuard sprays. Each fogger treats up to 625 sq. ft. in one application.

- SaniGuard PRO™ Salon Disinfectant and Manicure Jar - Modern designed options for more efficient brush and tool disinfecting. SaniGuard's trademark square jar is quickly becoming the industry's top choice nationwide.

- SaniGuard PRO Brush & Comb Tub™ - A one gallon plastic tub for large scale disinfecting, hair removal or sanitary storage of combs and brushes. SaniGuard Tubs provide an attractive design for any station and easy function for maintaining a sanitary service area.

“From SaniGuard PRO – the first high powered Hepatitis C rated liquid tool disinfectant with color options, to the industry's first Total Release Fogger for effectively treating entire rooms in just minutes to the most advanced Barrier Skin Cream that the industry has seen to date, SaniGuard is your source for superior salon and spa sanitization essentials that are priced right,” says David Harried, V.P. of Marketing. “SaniGuard Professional Salon Products help to protect your customers and your employees, while making it easier to meet tough state regulations. It's time to say so long to the outdated old blue formula and replace it with advanced protection.”

For more information on how SaniGuard Professional Salon Products can help you achieve the ultimate in clean for your salon or spa, please contact David Harried at 608.347.9003, [sales@saniguardpro.com](mailto:sales@saniguardpro.com) or visit us online at <http://saniguardpro.com>.

## ***Hepatitis B Spreading among R.I. Inmates***

*Source: turnto10.com.*

### *Brown Studies Prison Population*

Hepatitis B, a potentially dangerous virus, is spreading through Rhode Island's prison population.

Researchers at Brown University made the discovery while studying common infectious diseases at the Adult Correctional Institutions. They were surprised to learn how easily the virus has been spreading among inmates.

The research shows that 20 percent of the ACI population has hepatitis B.

"There's an epidemic of hepatitis B in this population, and that's really a tragedy because we have a highly effective and safe vaccine for hepatitis B," researcher Dr. Josiah Rich said.

Most of the female population at the ACI has been vaccinated against hepatitis B. Researchers are trying to secure funding to offer vaccinations to the entire male population.



Hepatitis B often attacks the liver. It is generally spread through blood, sexual contact and in rare cases, through saliva.

Researchers said that once inmates are released, the virus could spread into the general population.

### ***Bristol to Seek OKs for Diabetes, Hepatitis Drugs***

*Source: Reuters*

NEW YORK -- Bristol-Myers Squibb Co. on Thursday said it plans within the next six months to seek regulatory approvals for new drugs to treat diabetes and hepatitis B.

Company Chief Executive Peter Dolan told analysts in a conference call the company will seek approval for Muraglitazar, a treatment for adult-onset diabetes it intends to co-market with Merck & Co. Inc. . Some analysts expect the drug to post annual sales of over \$500 million by 2008, if approved.

Dolan said Bristol-Myers will also seek approval for Entecavir for hepatitis B. Wall Street expects the drug to post annual sales of well over \$500 million by 2008, if approved.

**July 30<sup>th</sup>, 2004**

### ***23 Hemophiliacs File Damage Suit for Tainted Blood***

*Chung Ah-young*

*Source: Korea Times*

Twenty-three hemophiliacs on Friday filed a class action against the government, demanding 1 billion won in compensation for their contracting hepatitis and AIDS virus from contaminated blood.

Lawyers of the Law Firm J. L. and members of the Korea Hemophilia Association (KOHEM) began the joint legal battle, claiming that the health authorities are responsible for 23 hemophiliacs' infection with hepatitis C.

A KOHEM official said that one third of the hemophiliacs, or 632 out of 1,704, are confirmed suffering from hepatitis C, which mostly results from blood to blood infection.

According to the J. L. lawyers, the authorities have turned a blind eye to safe testing methods and management of blood even though the existing blood test has been vulnerable to infection since the hepatitis C virus (HCV) test was introduced in 1990s.

The authorities have refused to conduct an epidemiological investigation for hepatitis C although it is worsening as a chronic disease, forcing 17 percent of hepatitis C patients to die from liver cancer, the KOHEM said.

Compared to the infection rate for ordinary people with hepatitis C, hemophiliacs are hundreds of times more prone to contracting the disease. The infection rate for ordinary people stands at 0.2-0.4 percent, and is on the decline every year, while hemophiliacs show 2.3 percent at the age



of 0-4, 2.4 percent at the age of 5-9, 63.3 percent at the age of 10-19 and 65.9 percent for those over 20.

Lawyers taking the compensation suits said that other hemophiliacs aside from 23 will join the class action in late August, adding that the amount of compensation, coupled with treatment expenses, might surge after finishing health check-ups for those patients.

The class action group, including the law firm and the KOHEM also urged authorities to take measures to improve the blood testing and management system.

The Ministry of Health and Welfare confirmed a total of more than 1,205 blood samples had been tainted by hepatitis and AIDS during the last decade due to mistakes by Korea National Red Cross officials. According to the authorities, 205 of those blood samples that tested positive for hepatitis B and C had been distributed.

Twenty-seven officials of the KNRC were indicted without arrest on charges of circulating improper blood on Thursday.

### ***U.S. Attorney to Announce Settlement with Drugmaker***

*Source: Reuters*

NEW YORK--- The U.S. Attorney's office in Philadelphia said on Friday it has reached a "significant settlement" of criminal and civil cases with a U.S. drugmaker.

A press conference will be held in Philadelphia later in the day.

The New York Times earlier this month said that Schering-Plough Corp. (SGP.N: Quote, Profile, Research), which has been under investigation for allegedly defrauding the government Medicaid insurance program by overcharging for its drugs, had reached a settlement with federal prosecutors.

Investors expect the company to be fined, and Schering-Plough has set aside \$500 million in reserves to cover expenses for this Medicaid case and other legal matters.

A spokeswoman for Kenilworth, New Jersey-based Schering-Plough, maker of the antihistamine Claritin and Peg-Intron for hepatitis C, said the company does not comment on ongoing investigations.