

# 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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April 25, 2009

## **Roche and Pharmasset Initiate Phase IIb Clinical Trial of R7128, Most Advanced Nucleoside Polymerase Inhibitor in Development for Chronic Hepatitis C**

<http://www.bio-medicine.org>

*Start of trial triggers \$10 million milestone payment to Pharmasset*

PRINCETON, N.J., April 24 /PRNewswire-FirstCall/ -- Pharmasset, Inc. (Nasdaq: VRUS) and Roche (Roche SWX: RO, ROG; Pink Sheets: RHHBY) today announced that the first patient has been dosed in a Phase IIb study of R7128, the nucleoside polymerase inhibitor most advanced in development for the treatment of chronic hepatitis C (HCV). The trial will evaluate the dose and duration of treatment of R7128 in combination with Roche's PEGASYS(R) (peginterferon alfa-2a) and COPEGUS(R) (ribavirin) - in HCV patients who have not been treated previously. The goal of adding R7128 to the existing standard therapy is to improve rates of sustained virological response (SVR) and to shorten the length of treatment for patients.

R7128 is being developed by Roche and Pharmasset under a partnership agreement entered into in 2004. The first patient dosed in this study triggered a \$10 million payment to Pharmasset from Roche.

A Phase I/IIa trial demonstrated the ability of R7128 to generate high rapid virologic response rates (RVR) in combination with PEGASYS and COPEGUS. Unlike protease inhibitors in development, R7128 is active against multiple HCV genotypes and presents a high barrier to the development of resistance.

"We look for the Phase IIb study to further support the efficacy and safety of R7128, and nucleoside polymerase inhibitors as a class," said Michelle Berrey, MD, MPH, Pharmasset's Chief Medical Officer. "We believe nucleoside inhibitors have a number of advantages over other classes of HCV drugs, including a higher barrier to resistance and activity across multiple genotypes, as well as a high level of potency."

*SOURCE Pharmasset, Inc.*

April 27, 2009

## **Millions of Hepatitis C Funding Dollars Misappropriated to HIV/AIDS**

<http://www.prweb.com>

Staunton, VA (PRWEB) April 27, 2009 -- The Hepatitis C Research Oversight Partnership (HepCop), has publicly denounced the National Institutes of Health (NIH) for misappropriating millions of dollars budgeted for research on the hepatitis C virus (HCV) -- already on a shoestring budget -- to funding for HIV/AIDS which has an enormous \$2.9 billion research allocation.

Statistics unearthed by HepCop show the NIH misrepresenting HCV research funding. For



example, hepatitis C grant money was awarded to determine such outcomes as, Couples-Based HIV/STI Prevention for Injecting Drug Users in Kazakhstan (\$676,058), Effects of HIV & Host Genetics in China (\$645,840), and Nutritional Status In HIV Hispanic Drug Abusers (\$660,216).

HepCop is also concerned that a possible conflict-of-interest exists. The NIH's National Institute of Allergy and Infectious Disease (NIAID) is charged with overseeing research on HIV and HCV. The NIAID's Director, Anthony Fauci, MD, is America's chief HIV/AIDS researcher who received an NIAID grant totaling \$183,959 from his Institute's paltry \$34 million HCV budget. HepCop contends Fauci should have funded his research from his Institute's \$1.3 billion HIV budget. The primary beneficiaries of Fauci's funding are not the many millions of patients solely infected with HCV, but rather only a few hundred thousand HIV patients who also have HCV.

HepCop points out that any suggested justification for redirection of HCV funds to additional HIV/AIDS research seems to be inconsistent with Fauci's own statement on CNN: "...the scientific advancements that have been made in HIV (research) are breathtaking (with) highly effective drugs to suppress HIV to the point where what was a death sentence in the early eighties to now having patients who look and feel well, who are leading very productive, very gratifying lives..."

The inescapable reality is that the HIV research has been so heavily funded that it reached its successful goal of developing life-saving drugs years ago. For example, the rate of AIDS deaths in California's newly infected patients has fallen 98 percent since 1992 from 9,797 deaths to 157 deaths in 2007 (as of 3/31/09).

HepCop spokesperson and past National Public Citizen of the Year (NASW), Dr. Richard Darling, DDS, who's HCV led to liver cancer, coma and three liver transplants states, "It is extremely disheartening to hepatitis C patients and their families that HCV funds have been redirected to HIV when the NIH is spending only \$20 per patient for HCV research compared to \$2,774 per HIV patient research. Finding out that a large portion of that \$20 is also being allocated for HIV research is a tragedy and an insult to HCV patients who are not suffering from HIV and who are waiting for the NIH to provide the research it promised."

William Remak, Chairman of the National Association of Hepatitis Task Forces and a two-time liver transplant recipient due to HCV is also angry: "This is an unconscionable state of affairs regarding hepatitis C and the impact it has had on the health of American taxpayers who fund the NIH."

Peter Fisher, an HCV patient and Founder of the Massachusetts Hepatitis Patient Empowerment Project calls it "A chilling example of how the politicization of infectious disease is killing people living with HCV."

HepCop points out that studies show as many as five million Americans are suffering from HCV, including two million veterans, whereas the estimated number of citizens with HIV is much smaller--just over one million. HCV is the leading cause of liver transplant and the first disease-producing virus to be designated as a carcinogen.

HepCop is urging restoration of the misappropriated funds by the NIH, and they will petition the Office of Government Ethics (OGE), Congressional Appropriations Committees and Senator

Chuck Grassley (R., Iowa) to begin an immediate investigation into HCV research funding and potential conflict of interest at the NIAID.

**Misappropriated HCV Funding is listed at**

[http://fairfoundation.org/NIH\\_misappropriated\\_funds.pdf](http://fairfoundation.org/NIH_misappropriated_funds.pdf) . Hepatitis C advocates wishing to join a petition to the OGE may do so at <http://www.hcvets.com/NIH/PressRelease/0904.asp> .

***Avila Therapeutics May Have Found “Achilles’ Heel” of Hepatitis C Virus***

<http://www.xconomy.com>

Ryan McBride

Avila Therapeutics emerged from stealth mode in December and told Xconomy about its secret sauce to systematically create permanent, covalent bonds with protein disease targets. Now the Waltham, MA-based biotech (pronounced AH-vill-uh) reports that its experimental drug for hepatitis C virus may be able to wipe out multiple variations and mutated forms of the virus.

The firm’s drug, dubbed AVL-181, is a small molecule protease inhibitor intended to silence a key protein for the survival and replication of the virus. The drug targets a region of the protein that the company believes is common among many known forms of the virus, even those that are resistant to standard treatments, meaning that the firm may have found an “Achilles’ heel” of the protein, says Nagesh Mahanthappa, vice president of business development and operations at the biotech. Over the weekend, the company presented results of a study, in which infected mice were treated with the drug, at the European Association for the Study of the Liver meeting in Copenhagen, Denmark.

“When we look across all known published genetic sequences of the hepatitis C protease, from a variety of mutants, we find that the particular site where we get bond formation with our drug is constant,” Mahanthappa says. “It remains possible that that site is somehow critical for the protease’s normal function, or the general fitness of the virus.”

It’s early in the game to draw any conclusions about Avila’s hepatitis C drug, which to date hasn’t yet advanced to clinical trials. Yet the fact that the startup may have found a new weakness in the virus, making the drug effective across drug-resistant and mutated strains, could help the drug stand out among the 40-odd other hepatitis C treatments in development. With industry embracing a cocktail approach to treating the disease, Mahanthappa says, there’s a possibility that Avila’s drug could be useful in combination with other drugs to combat difficult-to-treat variations of hepatitis C, which is a chronic liver disease that affects 170 million people worldwide.

The study presented over the weekend showed several potential benefits of Avila’s hepatitis C drug over existing treatments. For one, it had no significant impact on other proteins, boding well for how safe the drug could be for humans. Another potential perk is that the drug appears to work for 24 hours or more, meaning it could be taken once a day rather than several times a day. Yet there were many new hepatitis C drugs presented at the medical conference and most of the companies presenting those other drugs promised improvements over existing therapies as well. Cambridge, MA-based Vertex Pharmaceuticals (NASDAQ: VRTX) is generally considered the

front-runner in the race to develop the first protease inhibitor for hepatitis C, called telaprevir. That drug is now in the third and final stage of clinical trials needed before it can win FDA approval to start selling in the U.S.

For Avila, the hepatitis C protease inhibitor is one of two drugs that are neck and neck for top position in the biotech's young pipeline, Mahanthappa says. The other, called AVL-291, is a small molecule kinase inhibitor that could be used to treat immune system cancers such as non-Hodgkin's lymphoma and B cell chronic lymphocytic leukemia. The company's earlier plan was to begin human clinical trials of its hepatitis C drug by late 2009, but Mahanthappa says that the company now wants to wait until mid-2010 to start its first clinical trial. The company also hasn't decided which of its drugs to enter into clinical trials first. The reason for waiting an extra half year to begin clinical trials is to make the firm's existing capital last longer. The firm wants to raise more venture capital before it launches an initial clinical trial and—in case you've been living under a rock and don't know—the climate nowadays for completing such financings is pretty awful.

Avila is now in the midst of raising another round of financing, Mahanthappa says. The firm has previously received \$21 million in venture capital from lead investor Abingworth Management as well as Polaris Venture Partners, Atlas Venture, and Advent Venture Partners.

### ***Dynavax Presents Additional Phase 3 Data for HEPLISAV™ Hepatitis B Vaccine at EASL Medical Conference***

<http://www.businesswire.com>

BERKELEY, Calif.--(BUSINESS WIRE)--Dynavax Technologies Corporation (Nasdaq:DVAX) today announced the oral presentation of additional Phase 3 clinical data for HEPLISAV™ hepatitis B vaccine in a session for late-breaking abstracts at the 44th Annual Meeting of the European Association for the Study of Liver Disease (EASL) in Copenhagen, Denmark. As previously reported, HEPLISAV met its primary endpoint in this Phase 3 trial and demonstrated the vaccine's potential to provide more rapid and increased protection against hepatitis B viral infection and with fewer doses than the licensed vaccine.

This Phase 3 trial referred to as PHAST (Phase 3 Heparin Short-regimen Trial) evaluated more than 2,400 adults. The seroprotection rate at the primary endpoint was 95% in subjects receiving 2 doses of HEPLISAV at 0 and 1 month, compared to 81% in subjects receiving 3 doses of licensed vaccine Engerix-B® at 0, 1, and 6 months. At each time point, there was a statistically significant ( $p < 0.0001$ ) difference in the seroprotection rate for subjects receiving HEPLISAV or Engerix-B.

Treatment Group	Dosing Regimen	Seroprotection Rate <sup>(1)</sup> at Month				
		1	2	3	6	7
HEPLISAV	2 doses (0, 1 month)	24%	89%	95% <sup>(2)</sup>	98%	98%
Engerix-B	3 doses (0, 1, 6 months)	4%	26%	23%	32%	81% <sup>(2)</sup>

<sup>(1)</sup> Seroprotection rate – percentage of subjects with anti-HBsAg antibodies  $\geq$  10 mIU/mL

<sup>(2)</sup> Primary endpoint

As previously reported, safety results from this trial demonstrated the safety profile of HEPLISAV and Engerix-B appeared similar. Subjects were randomized 3 to 1 to receive HEPLISAV or Engerix-B and one case of vasculitis was reported in each of the treatment groups. Following the report of the severe adverse event of Wegener’s granulomatosis, an uncommon form of vasculitis, HEPLISAV was placed and remains on clinical hold by the U.S. Food and Drug Administration. Dynavax is clarifying the remaining regulatory requirements for the potential development and licensure of HEPLISAV in the United States and Europe.

A copy of the presentation is available at <http://investors.dynavax.com/events.cfm>. Dynavax’s abstract #587659 was titled “A Phase 3 Safety and Efficacy Study Comparing Immunogenicity of Two Doses of Hepatitis B Surface Antigen Combined with Immunostimulatory Sequence with Three Doses of Licensed Hepatitis Vaccine.”

### **About HEPLISAV**

HEPLISAV is a Phase 3 hepatitis B vaccine aimed at unmet medical needs in the vaccination of adults and end-stage renal disease patients by providing rapid and increased protection with fewer doses. HEPLISAV combines Dynavax’s proprietary immunostimulatory sequences (ISS), which target Toll-like Receptor 9, with hepatitis B surface antigen (HBsAg). HEPLISAV targets an estimated \$500 million global market opportunity for adult hepatitis B vaccines.

### ***North Dakota Observes Viral Hepatitis Awareness Month***

<http://www.emaxhealth.com>

In observance of National Viral Hepatitis Awareness Month in May, the North Dakota Department of Health is encouraging residents to learn more about the disease and to go in for testing if they are at risk for hepatitis, according to Sarah Weninger, Hepatitis Program coordinator for the Department of Health.

The following are the three most common types of viral hepatitis in the United States. All three can cause liver disease.

- Hepatitis A can last a few weeks to several months. The virus usually is spread when a person eats or drinks something contaminated with fecal matter of an infected person. The best way to prevent hepatitis A is by getting vaccinated.
- Hepatitis B can cause a mild illness lasting a few weeks to a serious, lifelong illness or even death. The virus usually is spread when blood or body fluid from a person infected with

hepatitis B enters the body of someone who is not infected. The best way to prevent hepatitis B is by getting vaccinated.

- Hepatitis C usually lasts a lifetime and can result in long-term health problems or even death. The virus usually is spread when blood from an infected person enters the body of someone who is not infected. There are treatment options available, but there is no vaccine for hepatitis C, so the best way to prevent it is to avoid behaviors that put you at risk.

Because most people who are infected with hepatitis have no symptoms, the Department of Health encourages anyone who has engaged in any of the following high risk behavior to consult with their health-care provider about being tested. Risk factors include:

- Sharing needles to inject drugs.
- Receiving blood products prior to 1992.
- Getting “home tattoos” or tattoos from unlicensed and unregulated tattoo shops.
- Having multiple sexual partners.
- Being born to an infected mother.

More than three million people in the United States have chronic hepatitis C virus infection, which is the major cause of chronic liver disease and the leading reason for liver transplantation. Additionally one in 12 people worldwide are living with either chronic hepatitis B or hepatitis C. Since 2005, an average of three people test positive for hepatitis A, 65 for hepatitis B, and 548 for hepatitis C each year in North Dakota.

In North Dakota, the following sites offer vaccinations to protect against hepatitis A and B and free testing for hepatitis C:

- Bismarck/Burleigh Public Health, Bismarck
- Central Valley Health Unit, Jamestown
- Custer Health, Mandan
- Fargo Cass Public Health, Fargo
- First District Health Unit, Minot
- Grand Forks Public Health Department, Grand Forks
- Lake Region District Health, Devils Lake
- Richland County Health Department, Wahpeton
- Southwestern District Health Unit, Dickinson
- Upper Missouri District Health, Williston

*Source: North Dakota Department Of Health*

**April 28, 2009**

## ***Amarillo Biosciences Supplies Oral Interferon For Taiwanese Hepatitis C Study***

<http://www.medicalnewstoday.com>

Amarillo Biosciences, Inc. (AMAR) (OTCBB: AMAR) today announced that clinical supplies were shipped to AMAR's partner in Taiwan, CytoPharm, Inc., to be used in a study of 165



patients with chronic hepatitis C virus infection. The aim of the trial is to reduce the virologic relapse rate for those patients who have completed the standard combination therapy, which consists of high dose injectable interferon alpha and Ribavirin. Although most patients respond to the standard therapy, up to 50% of those with certain viral genotypes relapse after treatment. The trial is expected to start in the second quarter of 2009 and to be completed in 2010. The patients will receive one of two different dosages of oral human interferon alpha or placebo daily for 24 weeks, followed by untreated observation for 24 weeks to check for relapse.

Approximately 170 million people are chronically infected with hepatitis C virus worldwide. The incidence of cirrhosis in chronic hepatitis C patients is 10 to 20%, and 1 to 5% develop liver cancer. Infections are transmitted primarily by direct contact with blood through transfusions not screened for hepatitis C virus, inadequately sterilized needles and syringes, sexual and perinatal transmission. There is no effective vaccine against hepatitis C virus.

In addition to studies on hepatitis C, under the terms of the License and Supply Agreement, CytoPharm will be testing oral interferon in human studies of chronic active hepatitis B and influenza.

*Source: Amarillo Biosciences, Inc.*

## ***Epileptic drug calms restless legs, improves sleep***

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

NEW YORK (Reuters Health) - The anti-seizure drug pregabalin (Lyrica) appears to help patients with restless legs syndrome get a better night's sleep. That's according to the findings of a clinical trial presented today at the annual meeting of the American Academy of Neurology.

Pregabalin, which is approved for the treatment epilepsy, neuropathic pain, generalized anxiety and fibromyalgia, was well tolerated by patients with restless legs syndrome and "is a promising alternative to current treatments because of its superior effects on quality of sleep," Dr. Diego Garcia-Borreguero, director of the Sleep Research Institute in Madrid, Spain, noted in a meeting statement.

The study involved 58 patients with restless legs syndrome of unknown origin. After 2 weeks on a placebo, 30 patients were assigned to receive pregabalin (150 to 600 milligrams daily) and 28 remained on the placebo for 12 weeks. Restless legs syndrome severity was determined periodically using the International Restless Legs Syndrome Rating Scale, as well as other disease severity measures; sleep studies were performed at the beginning of the study and again after 12 weeks.

According to Garcia-Borreguero and colleagues, the change in International Restless Legs Syndrome Rating Scale scores was significantly "more pronounced" with pregabalin than with placebo. With pregabalin, scores on this disease severity index declined from 19.8 to 6.8; with placebo, scores declined from 21.5 to 11.2.

Similar findings were obtained with other disease severity assessments, according to the investigators.

In addition, 63.3 percent of pregabalin-treated patients had remission of restless legs syndrome symptoms while taking the drug, at an average daily dose of 337 milligrams. In comparison, only 28.6 percent of placebo-treated patients achieved remission.

Pregabalin treatment also improved the sleep patterns in restless legs syndrome patients, who had a significant increase in time spent in deep slow wave Stage 3 sleep and a decrease in time spent in lighter stage 1 or 2 sleep, compared with the patients on placebo.

Due to its superior therapeutic effects on sleep, Garcia-Borreguero and colleagues conclude, pregabalin is a promising alternative to current drug treatments for restless legs syndrome.

## ***Cleaning Safety for Hepatitis C***

[www.hepatitis-central.com](http://www.hepatitis-central.com)

by Nicole Cutler, L.Ac.

Despite the claim that cleanliness is next to godliness, the products you use to keep your home clean may be worsening Hepatitis C. Particularly important for those with chronic liver disease, this informative article describes the most dangerous cleaning products and details how you can make toxin-free cleaning solutions.

Without a successful course of treatment, Hepatitis C often causes gradual, progressive liver damage. Thus, anyone living with this virus must take additional steps to protect themselves from toxins capable of causing additional liver injury. Unfortunately, potential liver hazard items can be found in all aspects of modern day life. Inside most people's homes, cleaning products harbor some of the most hazardous chemicals known. By reducing exposure to these toxins, those with Hepatitis C can protect themselves from unintentionally worsening their liver's condition.

Because the chemicals in cleaning products are not dispersed as easily indoors as outdoors, concentrations of toxic chemicals are highest indoors. According to a United States Environmental Protection Agency (EPA) report, dangerous compounds in the home may exceed the toxins found outside by up to 100 times or more.

Those with chronic Hepatitis C are more vulnerable to the toxins in cleaning products because:

- Chronic liver disease may have damaged portions of their liver, leaving fewer functioning cells to detoxify poisons.
- Chronic liver disease can cause liver inflammation, which diminishes the liver's ability to detoxify poisons.
- Scarring from chronic liver disease can interfere with circulation throughout the liver, leaving more toxins in the blood to further damage liver cells.

### **Dangerous Cleaning Products**

While there is a long list of potentially hazardous ingredients in cleaning products, the following appear to be some of the worst offenders:

**1. Air Fresheners and Deodorizers** – These products can contain hormone-disrupting

phthalates, cancer-causing chemicals such as formaldehyde and benzene, and other volatile organic compounds (VOCs) such as d-limonene that can irritate your eyes, skin and respiratory system, and cause headaches, nausea and dizziness.

**2. Alkyl Phenol Ethoxylates (APEs)** – Also known as surfactants, these chemicals are found in laundry detergents, all-purpose cleaners and stain removers. Unfortunate for those with diminished liver function, APEs break down into hormone-disrupting chemicals.

**3. Glycol Ethers** – Found in glass cleaners, floor cleaners and oven cleaners, glycol ethers can damage the nervous system, kidneys and liver, and be absorbed by the skin from the air.

**4. Petroleum Distillates** – Typically used as solvents, petroleum distillates are found in metal polishes and adhesive removers. They can cause temporary eye clouding, as well as long-term damage to the nervous system, kidneys and eyes.

**5. Phenol and Cresol** – Often found in disinfectants, phenol and cresol can cause diarrhea, fainting, dizziness and kidney and liver damage.

**6. Toilet Bowl Cleaners** – These emit naphthalene fumes, which can cause liver and kidney damage if ingested. Toilet bowl cleaners typically contain aradichlorobenzene, a toxin believed to cause cancer.

**7. Citrus** – Cleaners containing citrus can claim to be natural, but are often concocted with d'limonene, a chemical more toxic than toluene, which can damage bone marrow, liver and kidneys.

**8. Laundry Aids** – Fabric softeners and dryer sheets contain chemicals such as chloroform and benzyl acetate that are neurotoxic and carcinogenic. Exposure can be through inhalation or skin contact from dryer exhaust or from treated clothes, sheets and towels.

### **Toxin-Free Cleaning Solutions**

Those who are alerted to the dangers posed by cleaning products often purchase products from their local health food store. Luckily, several environment-friendly companies have identified the negligence of traditional cleaning product manufactures and offer alternatives for those concerned with toxin exposure. However, those on a budget may find the prices of toxin-free cleaning products to be significantly pricier than their traditional counterparts.

Fortunately, making your own supply of cleaners is relatively easy and inexpensive. Below are some recipes that can be confidently and safely used in the home of someone with Hepatitis C:

- **All-Purpose Cleaner** – To clean many hard surfaces (excluding marble), combine equal parts of white vinegar and water in a spray bottle.
- **Scouring Powder** – Mix 3 parts baking soda with 1 part borax. Keep handy in a shaker jar and use gloves when using, but keep away from children as it should not be ingested and may cause skin irritation.
- **Microwave Cleaner** – Put several slices of lemon in 1 microwaveable cup of water. Heat on high for three minutes, then let it sit for three minutes. Open up the microwave and wipe clean; the steam loosens any grime and the lemon kills germs and has a pleasant scent.

- **Mold and Mildew Remover** – Combine two teaspoons of tea tree oil in two cups of water in a spray bottle. Shake to blend and spray on problem areas. Do not rinse. The smell of tea tree oil is very strong, but will dissipate in a few days.
- **Furniture Polish** – In a glass jar, mix ½ teaspoon olive or jojoba oil with ¼ cup vinegar or fresh lemon juice. Dab a soft rag into the solution and wipe onto wood surfaces to polish.
- **Laundry Detergent** – Use 1/3 cup washing soda plus 1 ½ cup natural soap flakes. Add ½ cup Borax for whitening and softening. You can reduce the amount of cleaner needed by magnetizing your water using magnetic laundry disks or balls; these rip apart water molecule bonds to create ‘activated’ or ‘structured’ water and make it easier to remove dirt.
- **Dryer Sheets** – To eliminate static cling, toss a small wet towel into the dryer a few minutes before the end of the cycle.
- **Carpet Cleaner** – Sprinkle cornstarch on a dry carpet, leave on for five minutes and then vacuum.

Undoubtedly, there are many toxins in the average person’s arsenal of household cleaners. Since the ingredients in many cleaning products put an additional toxic load on the liver, people with Hepatitis C are advised to use cleaners made with non-toxic ingredients whenever possible. Besides buying products devoid of dangerous chemicals, making several of these simple, homemade remedies can help individuals with Hepatitis C keep within a budget, maintain cleanliness and protect their liver.

#### References:

<http://earth911.com/household/household-cleaners/facts-about-cleaning-products/>, Facts About Cleaning Products, Retrieved April 24, 2009, earth911.com.

<http://today.msnbc.msn.com/id/26903507>, The Dirty Truth About Cleaning Products, Retrieved April 24, 2009, Microsoft, October 2008.

[http://www.alive.com/1271a4a2.php?subject\\_bread\\_cramb=598](http://www.alive.com/1271a4a2.php?subject_bread_cramb=598) , So Clean, It’s Sickening, Michael Downey, BSc, Retrieved April 24, 2009, Alive Publishing Group, 2009.

<http://www.care2.com/greenliving/make-your-own-non-toxic-cleaning-kit.html> , How to Make a Non-Toxic Cleaning Kit, Annie B. Bond, Retrieved April 24, 2009, Care2.com Inc., 2009.

<http://www.healthyhepper.com/liverhazzards.htm> , Substances that are Harmful (or potentially harmful) to the Liver, Retrieved April 24, 2009, healthyhepper.com, 2009.

<http://www.sierraclubgreenhome.com/uncategorized/green-household-cleaning/>, Green Cleaning Supplies, Retrieved April 24, 2009, Sierra Club Green Home, 2009.

#### **Anadys: Too Early for HCV Drug**

<http://www.zacks.com>

Posted By: Grant Zeng, CFA

-- Highlights include Anadys Pharmaceuticals Inc. (ANDS), Roche Holding AG (RHHBY), Schering-Plough (SGP), Gilead Sciences (GILD), Vertex Pharmaceuticals (VTRX) and Valeant

*Pharmaceuticals International (VRX).*

*-- Strong efficacy data observed in early phase Ib studies for ANA598, but a severe rash raises safety concerns*

**ANA598** is Anadys' (ANDS) lead anti-HCV (hepatitis C Virus) drug candidate currently under phase I studies. The company's share price got a boost recently on its strong efficacy data from a phase Ib study.

Anadys presented the final antiviral and safety data from all three dose levels (200, 400 and 800 mg bid) at the 44th annual meeting of the European Association for the Study of the Liver (EASL) on April 23, 2009. The trial enrolled total 35 subjects. ANA598 treatment resulted in rapid and sustained reductions in HCV RNA with median reductions at end of treatment (day 4) exceeding 2 log<sub>10</sub> (>99%) at all dose levels.

At 200 mg bid, the median viral load reduction was 2.4 log<sub>10</sub> (range of 0.4 to 3.4); at 400 mg bid, 2.3 log<sub>10</sub> (range of 1.6 to 3.5); and at 800 mg bid, 2.9 log<sub>10</sub> (range of 2.2 to 3.4). Genotype 1a patients demonstrated median reductions of 1.4 log<sub>10</sub>, 1.8 log<sub>10</sub>, and 2.5 log<sub>10</sub> at 200, 400 and 800 mg bid, respectively. Genotype 1b patients demonstrated median reductions of 2.6 log<sub>10</sub>, 2.5 log<sub>10</sub> and 3.2 log<sub>10</sub>, at 200, 400 and 800 mg bid, respectively. Genotype 1b is the most common subtype of hepatitis C found in North America and Europe.

No patient showed evidence of viral rebound while on ANA598. The drug seemed well-tolerated in this short-term study and there were no serious adverse events reported.

However, later in a separate study from healthy volunteers in a 14-day study conducted to extend the safety and pharmacokinetic profile of ANA598, a severe rash was observed in some ANA598 treated subjects. Thirty subjects participated in the study, with eight subjects receiving ANA598 and two subjects receiving placebo at each dose level (400 mg once-daily, 800 mg once-daily and 600 mg bid).

Preliminary results from the study suggested that ANA598 was generally well-tolerated in all cohorts with no serious adverse events, but three subjects (two subjects in the 800 mg once-daily cohort and one subject in the 600 mg bid cohort) developed grade II rash and discontinued treatment after either six or seven days of consecutive dosing.

### **Competition is fierce in anti-HCV market**

Although ANA598 showed encouraging efficacy, this was only conducted in an early phase I trial with a very small number of patients. We remind investors that competition will be fierce in the anti-HCV market.

HCV is a serious infection afflicting about 3.2 million people in the U.S. and approximately 170 million people worldwide -- fatal in some cases -- and is the primary cause of liver transplants in the U.S. and Europe. This market is currently dominated by two players: Roche (RHHBY), which commands a majority of the U.S. and global pegylated interferon market share through the sale of Pegasys/Copegus, and Schering-Plough (SGP), through the sale of Peg-Intron / Rebetrol. The global HCV market in 2008 was between \$2 and \$3 billion and is expected to grow to \$4.4 billion in 2010 and \$8.8 billion in 2015.

Due to the asymptomatic nature of HCV infection, it often goes undetected for up to 20 years following the initial infection. Each year, 8,000 to 10,000 people in the U.S. die from complications of HCV. The current standard of care is a combination of pegylated interferon and ribavirin.

Even if Anadys is able to bring ANA598 to the market, it will face tough competition from other big players like Schering Plough, Roche, and Gilead (GILD) in the HCV market. In addition, a number of companies are developing oral formulations for the treatment of HCV.

Vertex (VTRX) has set a new benchmark for the treatment of HCV. Its HCV candidate, Telaprevir, demonstrated significant reduction in viral load with 4.4-log reduction in viral load compared to 1-2 log reduction seen in other standard of care interferon therapy.

We believe that this data sets the bar very high, and we are unsure whether Anadys can reach it. Currently, Telaprevir is undergoing phase III studies. Valeant's (VRX) Taribavirin (previously known as Viramidine) is in advanced clinical development.

Meanwhile, Schering's Boceprevir is in phase III. Hence, they are already ahead of Anadys in terms of development. So we believe competition will remain a challenge for Anadys in the years to come.

#### **Cash burn is a matter of concern**

The company is still in the development stage, with no products on the market.

Net cash burn in the first quarter of 2009 was \$7.1 million. The company had only \$21 million in cash, cash equivalents and investment as of March 31, 2009, which should last for about three quarters, according to our model. Anadys, therefore, needs to enter into an agreement on a partnership or acquisition relatively quickly otherwise it will have to raise additional cash to fund its operations in 2009.

Currently all eyes are on the ANA598 data and potential partnership agreement the company may enter into in the near future. We are happy to see the very positive efficacy data in the phase Ib trial, but are concerned about the severe rash side effect. Since the phase I trial is only tested in a small number of subjects, we remain skeptical if the company can find a partner with favorable terms.

**April 29, 2009**

### ***New England Journal Of Medicine Publishes Landmark Clinical Studies Of The Investigational Hepatitis C Virus Protease Inhibitor Telaprevir***

<http://www.medicalnewstoday.com>

Two clinical studies published in this week's *New England Journal of Medicine* demonstrate that treatment with the investigational oral hepatitis C virus (HCV) protease inhibitor telaprevir dosed in combination with pegylated-interferon (peg-IFN) and ribavirin (RBV) as part of a 24-week treatment regimen resulted in a significant improvement in the rate of sustained viral response

(SVR), considered a cure of the viral infection, in treatment-naïve genotype 1 HCV patients, as compared with the SVR rate for standard therapy dosed for 48 weeks. The data are from two Phase 2b (mid-stage) clinical trials of telaprevir known as PROVE 1 and PROVE 2. In these trials, patients who received a 24-week telaprevir-based treatment regimen achieved SVR rates of up to 69 percent, as compared to SVR rates of up to 46 percent in patients in the control arms of these trials who received peg-IFN and RBV for a standard duration of 48 weeks. Telaprevir is being developed by Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) in collaboration with Tibotec and Mitsubishi Tanabe Pharma. Telaprevir is currently in Phase 3 (late-stage) clinical development.

HCV is the most common blood-borne infection in the U.S., four times more common than HIV infection, and is the leading cause of liver transplantations and liver cancer in the U.S.

"Currently available therapies for patients infected with HCV can be difficult to tolerate and less than half the patients who start the yearlong treatment regimen achieve the ultimate goal of having an undetectable level of virus in their bodies," said John McHutchison, M.D., Lead Investigator for the PROVE 1 trial and Associate Director of the Duke Clinical Research Institute. "In these Phase 2 clinical trials, up to 69 percent of patients in the 24-week telaprevir-based treatment arm had undetectable virus levels after 24 weeks, and even though telaprevir does produce side effects of its own, its addition to standard therapy allowed us to shorten the duration of treatment. This 24-week regimen was half the duration of currently approved therapies and, if confirmed to be this effective in larger Phase 3 studies, could one day become a very important treatment option for hepatitis C patients."

"In the PROVE 1 and PROVE 2 trials, telaprevir significantly improved the proportion of patients who were cured of their disease and also shortened the duration of HCV therapy from 48 to 24 weeks for the majority of treatment-naïve patients - an exciting achievement and a potentially meaningful advance in the treatment of this disease," said Robert Kauffman, M.D., Ph.D., Senior Vice President of Clinical Development for Vertex. "Based on data from these trials, as well as from the PROVE 3 trial in patients who failed prior HCV therapy, telaprevir is being evaluated in a comprehensive Phase 3 registration program in more than 2,200 treatment-naïve and treatment-failure patients. Assuming successful completion of this program, we expect to file an application for approval of telaprevir with the U.S. FDA in the second half of 2010."

### **PROVE 1 and PROVE 2 Study Results**

The primary endpoint of the PROVE 1 and PROVE 2 trials was the proportion of patients who had no detectable hepatitis C virus in their blood (undetectable plasma HCV RNA) 24 weeks after the completion of therapy, also known as a sustained viral response (SVR). Patients who achieve an SVR are considered to be cured of their HCV infection.

Final results from the PROVE 1 and PROVE 2 trials showed that the 24-week treatment arm, which consisted of 12 weeks of telaprevir dosed in combination with peg-IFN and RBV followed by an additional 12 weeks of peg-IFN and RBV alone, resulted in a significant improvement in SVR rates, an increased rate of rapid virologic response (RVR, defined as undetectable levels of HCV RNA by the end of week 4) and low rates of viral relapse (defined in patients as undetectable HCV RNA at the end of treatment but detectable viral levels during the post-treatment follow-up period), as compared with the SVR, RVR and relapse rates observed in patients in the control arms who received peg-IFN and RBV for 48 weeks.

Of the small sub-group of African American patients enrolled in PROVE 1, 44 percent achieved an SVR in the telaprevir arms, while 11 percent achieved an SVR in the control group. SVR rates in African Americans are typically lower than in other ethnic groups. African Americans are also disproportionately infected with HCV as compared to other ethnic groups.

Together, these data suggest that a 24-week telaprevir-based treatment regimen may be sufficient for treatment-naïve patients who achieve an RVR. These findings are being confirmed in Vertex's ADVANCE Phase 3 clinical trial in treatment-naïve patients, focusing on 24-week response-guided regimens that consist of either 8 or 12 weeks of telaprevir in combination with peg-IFN and RBV. Treatment-naïve patients in the ADVANCE Phase 3 trial who achieve an RVR and who stay undetectable through week 12 of treatment will receive 24 weeks of treatment. Patients who do not meet the RVR criteria but are undetectable at week 24 will continue on peg-IFN and RBV for a total duration of 48 weeks. This Phase 3 trial is designed to maximize the number of patients who can achieve SVR while offering a large proportion of treatment-naïve patients the benefit of a 24-week treatment duration.

### **Telaprevir Safety & Tolerability Across PROVE 1 and PROVE 2**

More than 400 patients received a telaprevir-containing regimen as part of the PROVE 1 and PROVE 2 clinical trials, and the adverse event profile was generally consistent across these trials. Telaprevir was evaluated in combination with Peginterferon alfa-2a and ribavirin. In these placebo-controlled studies, the most common adverse events reported more frequently in the telaprevir treatment arms compared to the placebo arms were gastrointestinal events, skin events (rash, pruritus) and anemia. Other adverse events reported were similar in type and frequency to those seen with currently approved peg-IFN and RBV treatment. The most common adverse event leading to discontinuation in the telaprevir arms was rash in approximately 7 percent of patients across both PROVE 1 and PROVE 2. Investigators have reported that rash adverse events were reversible upon discontinuation of treatment, and a rash management plan was implemented as part of subsequent telaprevir clinical trials, including ongoing Phase 3 trials.

### **PROVE 1 Study Design**

PROVE 1 was a Phase 2b, randomized, double-blind, placebo-controlled trial that enrolled and treated 250 treatment-naïve genotype 1 HCV patients at 37 clinical trial sites in the U.S. Of the patients enrolled in PROVE 1, the mean age was 48.1 years, 63 percent were men and 77 percent were white. Patients in PROVE 1 received 750mg of telaprevir (or placebo) orally every eight hours, based on treatment arm, and a once-weekly 180ug injection of Peginterferon alfa-2a, as well as a 1,000mg or 1,200mg weight-based daily oral dose of ribavirin. PROVE 1 consisted of four treatment arms: (1) a 24-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN and RBV, followed by an additional 12 weeks of peg-IFN and RBV alone, (2) a 48-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN and RBV, followed by an additional 36 weeks of peg-IFN and RBV alone, (3) a 12-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN and RBV, and (4) a control arm consisting of 12 weeks of placebo in combination with peg-IFN and RBV, followed by 36 weeks of peg-IFN and RBV alone.

### **PROVE 2 Study Design**

PROVE 2 was a Phase 2b, randomized, partially double-blind, placebo-controlled trial that enrolled and treated 323 treatment-naïve genotype 1 HCV patients at 28 clinical trial sites in France, Germany, the United Kingdom and Austria. Of the patients enrolled in PROVE 2, the

mean age was 44.3 years, 59.4 percent were men and 94.1 percent were white. Patients in PROVE 2 received 750mg of telaprevir (or placebo) orally every eight hours, based on treatment arm, a once-weekly 180ug injection of Peginterferon alfa-2a, as well as a 1,000mg or 1,200mg weight-based daily oral dose of ribavirin. PROVE 2 consisted of four treatment arms: (1) a 24-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN and RBV, followed by an additional 12 weeks of peg-IFN and RBV alone, (2) a 12-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN and RBV, (3) a 12-week telaprevir-based arm consisting of 12 weeks of telaprevir in combination with peg-IFN (no RBV), and (4) a control arm consisting of 12 weeks of placebo in combination with peg-IFN and RBV, followed by 36 weeks of peg-IFN and RBV alone.

### **About Telaprevir and Vertex's HCV Development Portfolio**

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is one of the most advanced investigational antiviral agents in development that specifically targets HCV. Telaprevir is being evaluated as part of a global Phase 3 registration program in more than 2,200 treatment-naïve and treatment-failure patients.

Vertex retains commercial rights to telaprevir in North America. Vertex and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East and other countries. Vertex is collaborating with Mitsubishi Tanabe Pharma to develop and commercialize telaprevir in Japan and certain Far East countries.

Vertex is also developing **VCH-222**, an oral inhibitor of the HCV NS5B polymerase. HCV polymerase inhibitors represent an additional class of drug candidates that are aimed at inhibiting viral replication.

*Source: Vertex Pharmaceuticals Incorporated*

### **Senate supports bill to allow medical treatment with marijuana**

<http://www.citizen.com>

CONCORD – The Senate voted today, 14-10, in favor of legislation to help cancer patients and others treat debilitating symptoms with small amounts of marijuana with their doctor's approval.

“This is a bill of compassion,” said Senator Peggy Gilmour, D-Nashua. “With this bill, those who derive benefit from marijuana for serious health issues can be called ‘patients’ rather than ‘criminals.’”

Gilmour said marijuana has been found to alleviate the nausea triggered by certain chemotherapy and radiation treatments for cancer as well as to ease the side effects of treatment for Hepatitis C. It also reportedly can ease symptoms of AIDS, muscular dystrophy and muscle spasms associated with spinal cord injuries.

“Thirteen states have legalized marijuana for medical use. None has found increased abuse, increased crime or any of the myriad social ills or law enforcement nightmares so often feared. What they have found is one more way to help those with debilitating disease, those at life's end, find some increased measure of comfort,” Gilmour said.

House Bill 648 would allow patients, with the approval of their doctor, to receive a state registry identification card that enables them or a designated caregiver to tend up to six plants and keep up to two ounces of marijuana for a limited period of time. The marijuana could then be used to ease the symptoms of a debilitating disease or treatment. Sale of any marijuana would be forbidden but registered patients could legally provide plants or seeds to another registered patient.

The Senate version of the bill adds restrictions forbidding the use of medical marijuana in any public place, workplace, school or jail. It prevents anyone convicted of a drug-related crime of being named a designated caregiver. It protects the privacy of patients by limiting access to the state registry. It also sets up a study committee to look at a simpler, more protected system for providing medical marijuana to those who need it.

## ***Combined Maternal Treatment and Infant Vaccination Effective in Reducing Mother-to-Child HBV Transmission***

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

Becky McCall

April 28, 2009 (Copenhagen, Denmark) — Using a novel combination strategy — vaccination of infants born to women infected with hepatitis B virus (HBV) who had high levels of HBV DNA plus prenatal treatment of the women — might reduce the vaccine failure rate from 39% to 18%, according to new research presented here at the European Association for the Study of the Liver 44th Annual Meeting. These data confirm earlier data from the Netherlands that showed a risk reduction for vaccine failure from 28% to 13%.

The strategy was developed by Robert de Man, MD, PhD, associate professor from the Department of Gastroenterology and Hepatology, Erasmus University Medical Center in Rotterdam, the Netherlands, and colleagues.

HBV is most prevalent in Asia and sub-Saharan Africa, but is also found in migrant populations and second-generation immigrants in industrialized countries. One million people die each year from hepatocellular carcinoma caused by HBV, and it is the ninth leading cause of death worldwide. High-risk pregnant Chinese women with HBV have been shown in previous studies to experience an increase in gestational diabetes mellitus, an increase in antepartum hemorrhage, and a trend toward preterm labor. Infants born to mothers with acute HBV infection during pregnancy can experience low birth weight and premature delivery.

The child is also at risk. Pregnant women who are hepatitis B e antigen (HBeAg)-positive have a high chance of transmitting HBV to the baby during birth. Most cases of HBV mother-to-child transmission are controlled with a combination of active and passive immunization of the baby. But children born to mothers who are highly viremic for HBV (HBeAg-positive) have a 32% chance of becoming infected during birth, despite prophylactic vaccination and hepatitis B immunoglobulin. Data suggest that this occurs if maternal HBV DNA levels exceed 150 pg/mL ( $1.2 \times 10^9$  copies/mL).

"Most babies receive HBV perinatally, but without any treatment around 70% to 90% of babies will become infected if the mother has a heavy viral load," Dr. de Man told Medscape

Gastroenterology. He continued: "90% of these HBV-infected children will develop chronic HBV disease without intervention. This high chance of infection contributes to the continuing reservoir of ongoing disease. It is therefore essential to interrupt transmission at birth to lower total disease burden."

The study data show that infants born to women with high levels of HBV DNA can be treated using a different strategy. The pregnant woman should be treated during the last 4 to 6 weeks of pregnancy to lower the viral load, and postpartum, the infant should be immunized with vaccine and immunoglobulin, as should all infants born to HBV-infected women.

"The study results show that [the] 39% vaccination failure rate [is reduced] to 18% using this strategy. There is a clear group that benefits from this treatment," added Dr. de Man.

He emphasized that it is not clear whether maternal use of antiviral therapy is safe during pregnancy. Dr. de Man explained that despite limited data, a hepatic flare during pregnancy is dangerous for mother and child and that antiviral therapy in this setting is the outcome of a physician-patient decision made using the best information available.

There is no effective treatment for hepatitis B in either adults or children, so prevention of infection is essential. Deirdre Kelly, MD, professor of pediatric hepatology from the University of Birmingham in the United Kingdom, emphasized the need for prevention over cure. "Most of my new pediatric patients with hepatitis B are either new migrants from endemic areas who have not been vaccinated or children who have failed vaccination."

Dr. Kelly believes that effective antenatal screening is essential to identify at-risk women who need active support and management during pregnancy.

"In mothers who have high levels of HBV DNA, antivirals for the last trimester are of considerable value in preventing transmission. More clinicians should be aware of this treatment strategy and implement it. It is also vital that children of carrier mothers receive adequate vaccination with immunoglobulin and vaccine and are checked at 12 months to ensure that the vaccination has been successful," she concluded.

Dr. de Man also drew attention to the need to assess the status of liver disease in pregnant women. The woman becomes tolerant or there is no worsening of liver disease in the majority of women during pregnancy. Liver enzymes frequently normalize, he said.

However, postpartum, liver disease in the mother often becomes more active, with alanine aminotransferase levels flaring after delivery in around 40% of patients. He stressed the importance of monitoring the mother as well as the child. "The message is that all countries have screening programs at 12 to 16 weeks to detect hepatitis B in the mother and to be able to vaccinate the baby, but it is essential not to forget to evaluate the extent of the liver disease in the mother at 3 months after delivery. Many of these mothers are lost to care," Dr. de Man explained.

Dr. de Man and Dr. Kelly have disclosed no relevant financial relationships.

*European Association for the Study of the Liver 44th Annual Meeting: Symposium 7. Presented*

April 25, 2009.

May 1, 2009

## **Stop using Hydroxycut products, FDA says** *Story Highlights*

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

By Sandra Young

*--FDA recalls Hydroxycut products after 23 liver injuries and one death*

*--Hydroxycut products used as popular dietary supplement for weight loss*

*--Damage from product: liver failure, jaundice, seizures, cardiovascular problems*

WASHINGTON (CNN) -- Hydroxycut products, popular dietary supplements used for weight loss, have been linked to liver damage and are being recalled, the U.S. Food and Drug Administration said Friday.

The FDA has received 23 reports of serious liver injuries, including a death, linked to Hydroxycut products.

The FDA said it has received 23 reports of serious liver injuries linked to Hydroxycut products, which are also used as energy enhancers and as fat burners.

The reports include the 2007 death of a 19-year-old male living in the Southwest, which was just reported to the FDA in March. Other serious liver problems reported included liver damage that resulted in a transplant in 2002, liver failure, jaundice, seizures and cardiovascular problems.

The FDA is warning consumers to immediately stop using 14 Hydroxycut products manufactured by Iovate Health Sciences Inc. of Oakville, Ontario, and distributed by Iovate Health Sciences USA Inc. of Blasdell, New York.

The company is voluntarily recalling the following products: Hydroxycut Regular Rapid Release Caplets, Hydroxycut Caffeine-Free Rapid Release Caplets, Hydroxycut Hardcore Liquid Caplets, Hydroxycut Max Liquid Caplets, Hydroxycut Regular Drink Packets, Hydroxycut Caffeine-Free Drink Packets, Hydroxycut Hardcore Drink Packets (Ignition Stix), Hydroxycut Max Drink Packets, Hydroxycut Liquid Shots, Hydroxycut Hardcore RTDs (Ready-to-Drink), Hydroxycut Max Aqua Shed, Hydroxycut 24, Hydroxycut Carb Control and Hydroxycut Natural.

According to the FDA, last year, Iovate sold more than 9 million units of Hydroxycut products, which were distributed widely to grocery stores, health food stores and pharmacies.

"The FDA urges consumers to discontinue use of Hydroxycut products in order to avoid any undue risks. Adverse events are rare, but exist. Consumers should consult a physician or other health care professional if they experience symptoms possibly associated with these products," said Dr. Linda Katz, interim chief medical officer of the FDA's Center for Food Safety and Applied Nutrition.

Liver damage is rare, but patients who experienced problems were taking doses recommended on the product label, the FDA said. Symptoms include brown urine, nausea, vomiting, fatigue, stomach pain, itching and light-colored stools.

The FDA has not yet determined what specific ingredients are responsible for the problems, because the products contain a variety of overlapping ingredients and herbal extracts.

Dietary supplements sold before October 1994 are not required to undergo any FDA review before going to market. The Dietary Supplement Health and Education Act of 1994 (DSHEA) required manufacturers to ensure a supplement to be safe before marketing. But manufacturers still don't need to register a product with the FDA or get approval before selling a supplement.

The agency can take action against an unsafe supplement once it's on the market. Since December 2007, any serious adverse event reported to the manufacturer must now be reported to the FDA within 15 days.

## ***Do you LIVERight?***

<http://www.asianweek.com>

### *5K Run/Walk to Raise Awareness of Hepatitis B and Liver Cancer*

1 in 10 Asian Americans is chronically infected with the hepatitis B virus that causes 80% of all liver cancer deaths - and 2 out of 3 don't even know that they are infected.

San Francisco - April 27, 2009 - San Francisco's Golden Gate National Park is once again playing host to one of the world's only large-scale Asian American specific awareness events - LIVERight 2009. *Taking place May 2nd in Lindley Meadow of Golden Gate National Park*, LIVERight 2009 is a unique 5k run/walk event with a goal of raising awareness and education about the greatest health disparity between Asian Americans and the general population - hepatitis B. Responsible for up to a million annual deaths worldwide, hepatitis B, a vaccine-preventable virus, causes liver cancer and death and infects 1 out of 10 Asian and Pacific Islander Americans.

California State Majority Whip Fiona Ma, long-time ally in the fight against hepatitis B, as well as San Francisco Supervisor Carmen Chu will both be in attendance, helping to kick off the race.

The distressing realities about the prevalence of hepatitis B are being brought into a community-wide discourse, thanks to the efforts of the Asian Liver Center at Stanford University (ALC) and Answer to Cancer Foundation. Dr. Samuel So, director of the ALC, Stanford University professor and leading liver cancer and hepatitis B specialist, calls hepatitis B "the most neglected global epidemic." Over 350 million people are chronically infected worldwide.

The event hopes to increase awareness in the general public about hepatitis B, and strongly encourage all individuals to get tested for and vaccinated against the virus. Eighty percent of all liver cancer cases are caused by hepatitis B, and most liver cancer cases are rapidly fatal. Fortunately, we have the power to completely eliminate hepatitis B - an effective vaccine was developed over 25 years ago. However, no coherent, large-scale vaccination campaign has yet

been orchestrated. The Asian Liver Center is working to fight this neglected epidemic - to bring it into the public discourse so it is no longer neglected, and to work towards eradication so it is no longer an epidemic. Through community education and screening events, the ALC works to protect healthy individuals and identify infected individuals. "One-third of the Chinese population is 19 or under, so you potentially have 350 million unprotected kids," So declares. "You have to protect the kids."

LIVERight 2009 is on May 2nd, 2009, from 9am to 12pm, in Lindley Meadow in Golden Gate National Park.

Registration for LIVERight is now open! Families welcome! Please visit <http://liver.stanford.edu> for more information and to register. Advance registration is \$25 for individuals, \$20 for team members (a team is 5 or more individuals). Includes a free T-Shirt. Prizes and raffle items include passes to Great America, gift certificates to restaurants, and more!

### **About LIVERight**

LIVERight is a 5K run/walk hosted by the Asian Liver Center at Stanford University and Answer to Cancer with the goal of raising awareness about hepatitis B and liver cancer. Hepatitis B causes 80% of all primary liver cancer cases, and is considered the greatest health disparity affecting the Asian/Pacific Islander demographic. As many as 1 in 10 Asian Americans and 1 in 20 of all people worldwide are chronically infected with hepatitis B. Nearly 1 million infected individuals die every year. Our ultimate goal is to eradicate hepatitis B. LIVERight 2008 attracted over 600 runners and 100 volunteers, and raised over \$100,000 to fight liver cancer and hepatitis B.

### **About the Asian Liver Center at Stanford University**

The Asian Liver Center at Stanford University (ALC) is the first non-profit organization in the United States that addresses the high incidence of hepatitis B and liver cancer in Asians and Asian Americans. Founded in 1996, the center uses a three-pronged approach towards fighting hepatitis B through outreach & education, advocacy and research. The Asian Liver Center spearheads educational outreach and advocacy efforts in the areas of hepatitis B and liver cancer prevention and treatment, serves as a resource for both the general public and health practitioners, and implements clinical and research programs.

If you would like more information about hepatitis B, the Jade Ribbon Campaign, or the Asian Liver Center at Stanford University, please visit <http://liver.stanford.edu>.

### **About Answer to Cancer Foundation**

The Answer to Cancer run was founded by Adrian Elkins, a 20-year old student at Southern Oregon University who was diagnosed with liver cancer in October 2002. Adrian passed away only eight days after the first annual Answer to Cancer Race on August 11, 2003.

### **The Answer to Cancer Foundation was created to**

1) provide funding and assistance to research-based cancer programs and institutions as well as educationally-focused cancer programs, associations and organizations; 2) garner awareness and public focus on the necessity for cancer research, trials and experiments in developing treatments and an eventually finding a cure for cancer; and, 3) educate the public about screening, high-risk factors and potential preventable measures associated with primary liver cancer.

## ***AIDS activist Dan Cusick, former Long Beach resident, 50***

<http://www.contracostatimes.com>

By Phillip Zonkel, Staff Writer

Dan Cusick Longtime San Francisco-AIDS activist and former Long Beach resident Dan Cusick died April 23 from complications related to Hepatitis C.

Cusick was 50 years old.

Cusick could not take Hepatitis C medicine - it would trigger his epilepsy and cause severe seizures, friends and family said - and he was awaiting a liver transplant.

When he passed away, Cusick was surrounded by his five brothers and two sisters, family members said.

In San Francisco, Cusick, who was long-time HIV survivor, worked with HIV-treatment advocacy organizations and people in recovery from drug addiction. He also managed the Castro County Club, a well-known coffee house in the city's Castro District.

"I championed for Dan. I was always proud of him," said his sister, Pat, 60, who resides in Lakewood. "He stood up for the homeless, gay people, alcoholics and drug users and wanted to help them."

Cusick spent his early years in Lakewood - graduating from Lakewood High School - and then moved to Long Beach, eventually living in Belmont Heights.

After attending Long Beach City College, Cusick worked at Ripples and then the Hyatt Regency Long Beach.

After 31 years in the Long Beach area, Cusick moved in 1990 to San Francisco. Early access to combination antiretroviral therapies in the mid-90s allowed Cusick, who was diagnosed HIV+ in 1986, to survive even though he was infected with PML, a once fatal AIDS-related viral disease.

After arriving in the Bay Area, Cusick devoted his life to the fight against HIV-AIDS and support people in recovery from drug addiction, friends said.

Cusick became a member of ACT UP/Golden Gate, later renamed Survive AIDS, an AIDS activist group that engaged in nonviolent civil disobedience.

Shortly after joining ACT UP/Golden Gate, Cusick began volunteering at Project Inform, one of the nation's oldest community-based HIV treatment advocacy organization, friends said.

Cusick counseled individuals around the country on the group's hot line and assisted the agency in its advocacy for effective treatments against HIV/AIDS, friends said.

A memorial service will be held May 30 at the Most Holy Redeemer Catholic Church, 100 Diamond St., San Francisco.

Donations can be made to the Castro Country Club, 4060 18th Street, San Francisco, 94114.