

HCV ADVOCATE WEEKLY NEWS REVIEW

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

*Alan Franciscus
Editor-in-Chief*

Week Ending: September 27, 2008

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Sep 21, 2008

UCSF Celebrates 45th Anniversary of Transplant Service

<http://www.marketwatch.com>

SAN FRANCISCO, Sep 19, 2008 (BUSINESS WIRE) -- As a world leader in organ transplantation, UCSF will celebrate its 45th year of transplantation with a week of exciting workshops, lectures and forums.

"Virtually every single person in this country knows someone who has end-stage organ disease and who could benefit from transplantation," said Nancy Ascher, MD, PhD, chair of the department of surgery. "UCSF has premier programs in transplantation of virtually all the solid organs. Our expert teams of specialists provide outstanding patient care. They offer even the most seriously ill patients the best chance of successful outcomes, and ensure patients' lives after transplant are as normal as possible."

During Transplantation Week from September 22-28, 2008, UCSF will host a number of events open to the public with topics including nutrition, sexuality after transplant, Hepatitis B and C awareness and screening, fitness and transplants, and HIV and transplantation. There will also be a forum for living donors, as well as a liver transplant celebration for 2,000 patients who have received a liver transplant at UCSF during the last 20 years.

Since performing its first kidney transplant in 1964, UCSF has performed transplants on more than 10,000 patients--enough to fill every seat in Davies Symphony Hall three times over; the kidney transplant program is one of the largest in the world. This spring, UCSF performed its 500th transplant in its heart and lung program and performs more than 500 transplants per year, including 360 kidney, 160 liver, 22 heart, 35 lung, 15 pancreas, and 10 islet cell transplants.

In addition, UCSF's world-renowned physicians engage in novel research that not only helps transplant patients, but also improves health outcomes for all patients. These discoveries have helped reduce the number of transplants that become necessary, and have shed new light on the biology of diseases such as Hepatitis C and HIV.

The field of transplantation has evolved with astonishing speed: the first transplant in the world was performed in 1954, and as recently as the early 1980s, the one-year survival rate for liver transplant recipients was only 20%. Today, that survival rate has risen to 90%. UCSF's transplant survival rates are comparable or superior to the average in every area, even though UCSF treats some of the most seriously ill patients. Some of UCSF's other transplant innovations include:

- Living donor program, in which healthy donors can donate one kidney or part of their liver to a transplant patient.
- Paired donor exchange, in which UCSF matches a donor and recipient pair with incompatible blood types with another donor-recipient pair, enabling two recipients to receive organs with perfectly matched blood types.
- HIV and transplantation: UCSF has pioneered the successful kidney, liver, pancreas and islet transplantation of HIV+ patients.
- Islet transplantation, in which patients receive the insulin-producing cells from a donor's pancreas, virtually curing them from diabetes.

For more information about Transplant Week at UCSF:

<http://transplant.surgery.ucsf.edu/celebrate.aspx>.

SOURCE: UCSF

UCSF

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Life or liberty?

<http://www.gallupindependent.com>

By Elizabeth Hardin-Burrola

Staff writer

GALLUP — Martin Morales' wife and children are praying for a miracle.

Morales, 42, a local contractor who has lived in Gallup for the last 28 years, has liver disease from hepatitis C SanvilleA 9/19/08 cq and is in dire need of a liver transplant. Last week he was hospitalized at Rehoboth McKinley Christian Hospital in Gallup. Now he's in Albuquerque's Presbyterian Hospital.

Family, friends, fellow church members, and concerned community members are frantically working to tell his story, raise money for his medical care, and assist this father of four who has no health insurance, but who faces a mountain of medical and legal challenges.

Transformed life

From his hospital bed last weekend, Morales, accompanied by his wife, Michelle, talked about his need for a transplant. Daughters Racquel and Chantelle, both 18, Yvonne, 17, and only son Martin, 13, listened quietly as their parents discussed the medical crisis that has rocked their family.

Originally from Mexico, Morales came to the United States as a young teen, searching for his father who had come to work in the U.S. Morales ended up in Gallup, where he found employment in the construction field. He eventually met and married Michelle and established his own construction business, known particularly for his stucco work.

There were, however, serious missteps along the way. As a teen, Morales explained, he became involved in drugs. His drug use led to arrests and a felony conviction, and that led to a stint in the New Mexico prison system.

But all those years of hard times also led Morales and his family to where they are now — a family solidly grounded in their love for God and for each other. Martin and Michelle became Christians, joined the Gallup Christian Center, and began raising their children in a far different way than they once had. They started hosting Bible studies in their home, and they began helping with men's and women's Bible studies in the McKinley County Adult Detention Center. In addition, Martin started visiting the local juvenile detention center, where he would share his anti-drug message and his personal testimony of faith.

As part of his effort to clean the slate of his past and live a new life, Morales said, he went to court officials several years ago to take care of an old arrest warrant, and he and Michelle hired an attorney to help him apply for U.S. citizenship.

And then he began to feel sick.

Life-changing diagnosis

It was two years ago, Michelle said, when she noticed something appeared wrong with her hardworking husband.

“He’s a very active person, and I noticed his energy level had dropped,” she explained.

Feeling weak and feverish, Morales thought he just had the flu. When the symptoms persisted, medical tests revealed Morales had hepatitis C, a virus that frequently produces no signs or symptoms during the early stages.

A person can unknowingly have hepatitis C for two or three decades while the disease silently attacks the liver. It eventually can lead to liver cancer, liver failure, or cirrhosis. One new treatment development, one that the Morales family is pinning its hopes on, is a liver transplant that involves the donation of a liver segment from a living family member.

Morales isn't sure how he contracted hepatitis C. The results of medical tests conducted after he quit using drug leads him to believe drug use wasn't the cause. He thinks he may have gotten the disease from unclean tattoo needles.

After his diagnosis, Morales began receiving medical care but continued to work and support his family. Two months ago, however, his health dramatically worsened, and he's been in and out the hospital ever since. According to Michelle Morales, all the doctors have agreed that at this stage in the disease, her husband only has a short time to live without a liver transplant.

“We’re talking months,” she said, “months that we need to get this done.” According to Michelle, after phone calls to the Mayo Clinic in Scottsdale, the family will need \$20,000 for the preliminary tests on Morales and potential family donors, another \$150,000 to get on the clinic’s waiting list, and another \$255,000 for the liver transplant.

Community support

A legal Catch-22 SanvilleA 9/19/08 cq has added another complicating layer to Morales’ medical crisis. He hasn’t been able to get medical insurance because he’s not an American citizen. He’s tried to apply for citizenship in the past, he said, but his felony conviction has been a stumbling block. He wanted to apply for a pardon for the felony, but the attorney he hired to help him with the pardon and the citizenship application suffered a stroke and is no longer able to practice law.

As a result, friends of Morales have begun a flurry of activity to help him and his family. A bank account, “Morales Family Medical Fund,” has been set up at the First Financial Credit Union, which has two locations in Gallup and branches in Pine Hill and Zuni. According to bank officials, the IRS is allowing the donations to be tax deductible. A Web site, www.supportmartinmorales.com, has been launched to accept Pay Pal and credit card donations. Petitions asking Gov. Bill Richardson to grant Morales a pardon are circulating around Gallup and can be signed at D&D Motors, the New Mexico Motor Vehicle Department, Pronto Plumbing, The UPS Store, and Xtreme Cuts.

Sandra Diaz, a family friend, has been involved in all these efforts. While circulating petitions around Gallup, she enlisted the help of Michael E. Lunnon, the owner of the Gallup UPS Store. Lunnon suggested setting up the bank account and Pay Pal account, and allowed one of his employees to create a flyer, an e-mail account, and the Web site for the medical fund.

Although Lunnon admits Morales’ immigration status is a tough issue for some, he believes Morales’ life is now an asset to the Gallup community.

“He’s paid his debit to society,” Lunnon said. “He deserves a second chance.” “I just hope the town can get behind him... and give him the help he needs,” he added.

From his hospital bed last weekend, Morales asked for people to pray for him and his family. “I always tried to help others,” he admitted, “but I never expected to be in this position.”

Michelle Morales said she and her husband have “totally surrendered” his medical condition to God and that they are spiritually at peace. “We trust and love God enough to know that he’s looking out for us,” she said.

And in a telephone call on Friday evening, she expressed gratitude to the people who have offered assistance, saying, “God has really blessed us with some great people.”

How to help

- Tax deductible donations made out to the “Morales Family Medical Fund,” can be delivered to any area branch of First Financial Credit Union or mailed to : First Financial Credit Union, 313 S. Boardman, Gallup, NM 87301.

- Tax deductible credit card or Pay Pal donations can be made on the Web site: www.supportmartinmorales.com
- Petitions asking Gov. Bill Richardson for a pardon can be signed at: D&D Motors, 400 W. Highway 66; New Mexico Motor Vehicle Dept., 1710 E. Aztec; Pronto Plumbing, 516 W. Wilson; The UPS Store, 2418 E. Highway 66; and Xtreme Cuts, 808 N. Highway 491.
- E-mails and letters on Martin Morales' behalf can be sent to Gov. Bill Richardson at his Web site (www.governor.state.nm.us) or sent to him at: Office of the Governor, 490 Old Santa Fe Trail, Room 400, Santa Fe, N.M. 87501

Information: www.supportmartinmorales.com

Author gives view from addiction to redemption

<http://newsok.com>

By Linda Miller
Staff Writer

A bad mood consumed Christopher Kennedy Lawford even before the telephone rang.

The caller wanted to write a book about what it's like to be a Kennedy now.

Lawford immediately wondered why the world needed another book about the Kennedys. And the call didn't improve his mood. He said he was being treated for hepatitis C, and anger and fear fueled his emotions.

Then he started thinking maybe he should write his own story. "I didn't know if I had a story to tell," he said.

"Symptoms of Withdrawal: A Memoir of Snapshots and Redemption" was published two years ago, and since then he's been traveling across the country offering a message of survival and hope.

He'll be in Oklahoma City on Oct. 14 for "An Evening of Courage and Inspiration," a benefit for Oklahoma Outreach Foundation.

Lawford, 53, is the son of actor Peter Lawford and Pat Kennedy Lawford. He grew up in Hollywood and Washington, a privileged child who started abusing drugs and alcohol when he was 13.

Though he didn't realize it at the time, genetics weren't on his side. Addictive behaviors clung to the family tree. In the late '60s and '70s, people were experimenting with sex and drugs, and there was little understanding about the downside of such behavior, he said. Drugs and alcohol blurred his personal circumstances — divorced parents and the murders of two of his family members.

He abused substances for 17 years, "until I did get sober at the age of 30. I've been sober for 22 years."

Lawford's resume includes political positions as well as acting credits, but what pushes him each day is talking about his life and establishing a career as an author.

"It turned out I had a story to tell, and I told my story," he said.

The follow-up is "Moments of Clarity," a book about spiritual epiphanies that allow people to move from addictions to recovery.

Lawford's moment of clarity came Feb. 17, 1986. Something allowed him that day to do what he had not been able to do for years.

"I had been trying for nine years to get sober," he said.

Many people say addicts don't try that hard, but that's not his experience. He said he desperately wanted to be sober and tried various methods, but none took hold.

"What happened ... was a surrender of some kind that I can't explain," he said. "You give up and become willing to do something you've never done in your life."

"An Evening of Courage and Inspiration"

- **Featuring:** Christopher Kennedy Lawford.
- **When:** 6:30 p.m. Oct. 14 at the Skirvin Hilton hotel.
- **Honoring:** Chesapeake Energy Corp. and its employees, recipient of the Dare to Believe Award.
- **Presented by:** Oklahoma Outreach Foundation, a nonprofit organization that provides funding for substance abuse treatment for adolescents who cannot afford quality care. Lawford also will visit Oklahoma Outreach Sober School, one of the foundation's programs.
- **Cost:** \$125. For tickets, call 842-0706.

Sep 22, 2008

SciClone Provides Promising Results From Its Phase 2A Clinical Trial Using SCV-07 as a Monotherapy in Patients With Chronic Hepatitis C Infection

<http://www.marketwatch.com>

SCLN 1.30, +0.03, +2.4%) today announced promising results from its proof-of-concept phase 2 clinical trial using its proprietary, immunomodulatory compound SCV-07 as a sole agent administered to patients chronically infected with the hepatitis C virus (HCV). The trial was designed to evaluate the effect of **SCV-07** on hepatitis C viral load, as well as on other measures of immune response. SCV-07 demonstrated activity in some treated patients in the higher dosage groups, and the decrease in viral load in these patients was accompanied by an increase in an

immunological biomarker which is usually correlated with response against HCV. Additionally, SCV-07 was shown to be generally safe and well-tolerated with no dose limiting toxicities or serious adverse events reported.

"In this study, SCV-07 demonstrated encouraging antiviral activity in patients who were previous relapsers to treatment," said Friedhelm Blobel, Ph.D., President and Chief Executive Officer of SciClone. "This is particularly exciting as patients were treated with only 7 days of monotherapy. Based on the promising outcome of this trial, SciClone plans to investigate further SCV-07's potential to prime the human immune system against HCV and plans to discuss with the FDA the initiation of a follow-up phase 2B trial. The follow-up trial may also be used to determine whether SCV-07 is capable of replacing or improving the response to current standard of care treatment. We are also pleased by the lack of side effects seen during treatment with SCV-07."

This randomized, placebo-controlled trial enrolled 34 patients infected with the difficult to treat genotype 1 strain of HCV, who had previously responded to treatment with interferon alpha and ribavirin but subsequently relapsed. Patients were randomized into three cohorts of escalating doses, and received daily subcutaneous injections of SCV-07 or placebo. After completing seven days of therapy, all patients were monitored for a further 7 days and patients in the highest dosage group were monitored for 30 days following end of treatment.

The primary objective of the trial was to assess the antiviral effect of SCV-07 on hepatitis C viral load and the pharmacodynamic effect as assessed by various biomarkers. In chronically infected patients, without treatment, variations in the amount of circulating HCV typically do not vary by more than 0.3 log. In this trial, reductions of greater than 0.6 log were seen in more than 10% of treated patients.

"SCV-07 has been shown to bind to macrophages and inhibit STAT-3 dependent responses, leading to stimulation of the Th1 immune response," said Israel Rios, M.D., Senior Vice President and Chief Medical Officer of SciClone. "A Th1 immune response is typically correlated with improved response in HCV patients. Additionally, neopterin levels are usually increased in connection with the stimulation of the Th1 immune response. In this trial, we have seen increased neopterin levels accompanying reduction in viral loads."

About SCV-07

SciClone's proprietary drug candidate SCV-07 (gamma-D-glutamyl-L-tryptophan) is a synthetic peptide with proven immune stimulating effects. SCV-07 has shown efficacy in treating various viral and bacterial infections. SCV-07 specifically stimulates the immune system through its effects on T-helper 1 cells, which are essential for clearance of viral infections. In June 2007, SciClone reported that SCV-07 also inhibits melanoma tumor growth, a cancer known to be sensitive to immune modulation, in an animal model study. Additional preclinical studies with SCV-07 are ongoing. For more information about SCV-07, please refer to the SciClone press release dated June 27, 2007.

About Hepatitis C Virus

HCV is a viral disease which attacks the liver and can lead to cirrhosis of the liver, liver cancer, and death. According to the Centers for Disease Control and Prevention, approximately 3.2 million individuals in the United States are chronically infected with HCV. Approximately 75%

of these chronically infected carriers are infected with the difficult to treat genotype 1 strain of the virus. Unfortunately, currently approved therapy, including the immunotherapy interferon alpha with or without the antiviral drug ribavirin, has significant side effects and is ineffective in treating most patients infected with HCV genotype 1.

About SciClone

SciClone Pharmaceuticals is a biopharmaceutical company engaged in the development of therapeutics to treat life-threatening diseases. SciClone's lead product ZADAXIN(R) is currently being evaluated in a late-stage clinical trial for the treatment of hepatitis C, and successfully completed a phase 2 clinical trial in malignant melanoma. ZADAXIN is approved for sale in select markets internationally, most notably in China where SciClone has an established sales and marketing operation. A key part of SciClone's strategy is to leverage its advantage and broaden its portfolio in the rapidly growing Chinese market by in-licensing or acquiring the marketing rights to other products, such as DC Bead™. SciClone's other clinical-stage drug development candidates are RP101 for the treatment of pancreatic cancer and SCV-07 for the treatment of hepatitis C. For more information about SciClone, visit www.sciclone.com.

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SOURCE: SciClone Pharmaceuticals, Inc.

Infection with hepatitis C virus (HCV) may suppress co-infection with hepatitis B virus (HBV) during acute or chronic HBV infection.

www.newsrx.com

New hepatitis B virus findings from F.C. Tseng and co-authors described.

“Infection with hepatitis C virus (HCV) may suppress co-infection with hepatitis B virus (HBV) during acute or chronic HBV infection. We examined relationships between HBV infection, HCV infection and other factors among injection drug users (IDUs) with antibodies to both viruses,” researchers in the United States report.

“Participants enrolled in a cross-sectional study during 1998-2000 were considered to have been infected with HBV if they had core antibody, to be chronically infected if they had hepatitis B surface antigen (HBsAg), to have been infected with HCV if they had HCV antibody and to be chronically infected if they had HCV RNA. Among 1694 participants with antibody to both viruses, HBsAg prevalence decreased with increasing age among those positive for HCV RNA [from 4.55% in those 18-29 years to 1.03% in those \geq 50 years old (P-trend = 0.02)], but not among those who were negative for HCV RNA. Chronic HBV infection was less common overall among those with chronic HCV infection (odds ratio [OR], 0.25; $P < 0.0001$), but this inverse relationship was much stronger in the oldest (> 50 years; OR = 0.15) than the youngest (18-29 years; OR = 0.81) participants (P-trend = 0.03). Similar results were obtained when duration of injection drug use was substituted for age (P-trend = 0.05). Among IDUs who have acquired both HBV and HCV, chronic HBV infection is much less common among those with

chronic HCV infection, but this inverse relationship increases markedly with increasing years of age and injection drug use," wrote F.C. Tseng and colleagues.

The researchers concluded: "Co-infection with HCV may enhance the resolution of HBsAg during the chronic phases of these infections."

Tseng and colleagues published their study in the *Journal of Viral Hepatitis*: The inverse relationship between chronic HBV and HCV infections among injection drug users is associated with decades of age and drug use. *Journal of Viral Hepatitis*, 2008;15(9):690-698).

For additional information, contact F.C. Tseng, National Cancer Institute, Division Cancer Epidemiology & Genetics, Advanced Technology Center, Room 225A, MSC 4605 8717, Grovemont Circle, Bethesda, MD 20892, USA.

CDC recommends Asian, African immigrants be tested for hepatitis B

<http://www.news-medical.net>

According to new guidelines CDC officials made public on Thursday, people born in either Asia or Africa who currently live in the U.S. should be tested for hepatitis B, the *San Francisco Chronicle* reports.

Other "at-risk" groups, such as injection drug users and men who have sex with men, also should be tested, the guidelines say. The announcement was made during a news conference at the San Francisco-based Chinatown Public Health Center.

While previous guidelines have focused on screening and testing, the new guidelines focus on treatment, education and the long-term care of those with the disease, the *Chronicle* reports.

San Francisco is a "gateway for immigrants from China and other Asian countries" that have a high hepatitis B prevalence, and the city also has the nation's highest rate of liver cancer, according to the *Chronicle*. The disease affects an estimated 25,000 Asian-Americans/Pacific Islanders in the city. Nationwide, one in 12 Asian-Americans/Pacific Islanders has hepatitis B, according to CDC. The city also was chosen in part because of the success of a hepatitis B awareness campaign, which has vaccinated 4,000 residents since April 2007.

State Assembly member Fiona Ma (D), who was diagnosed with hepatitis B at age 22, said, "Our culture is not to talk about disease. People should not keep this a secret," adding, "I was walking around for 20 years not knowing what to do about my own health. I have a one in four probability of developing liver cancer. I'm hopeful that the disease won't affect me in my lifetime" (Fernandez, *San Francisco Chronicle*, 9/19).

Sep 23, 2008

Hepatitis C sufferers miss out on treatment

<http://www.theage.com.au/>

Julia Medew

September 24, 2008

HEPATITIS Australia has called for urgent action to assist people with hepatitis C after new figures revealed more than 98% of the 200,000 Australians living with the virus did not receive any treatment last year.

Despite an available cure for many cases, the number of people with severe liver disease as a result of untreated hepatitis C has risen from 35,900 to 47,600 in the past five years.

Helen Tyrrell, head of Hepatitis Australia, said she was alarmed by new figures from the National Centre in HIV Epidemiology and Clinical Research that showed only 3539 people, or 2% of Australians with hepatitis C, accessed treatment last year.

"In contrast, around 65% of the estimated 16,692 Australians living with HIV received antiretroviral treatment in 2007," she said. "Treatment isn't for everyone, but people living with hepatitis C need to be aware effective treatment is available so they can make an informed decision about what is right for them."

Ms Tyrrell urged governments to develop awareness campaigns about treatment options and improve access to specialist medical and nursing staff.

She said prisons, which had a high number of hepatitis C patients, and GPs also needed to be educated about treatment and referral options for patients.

"We have a situation where the barriers to hepatitis C treatment have not been adequately addressed," she said.

Ms Tyrrell said hepatitis C - a blood-borne virus that attacks the liver, and in some cases, leads to cirrhosis, liver cancer and death - could be cured with drugs in up to 80% of cases. If left untreated, severe liver damage could lead to a long wait for a liver transplant and no other treatment options, she said.

Symptoms of hepatitis C include fatigue, flu-like symptoms, abdominal pain, nausea, depression and joint and muscle pain.

China warns of tougher punishment for bad blood

<http://www.iht.com>

The Associated Press

BEIJING: Agents who collect or supply blood that causes death or serious illness face stricter punishments starting Tuesday in an attempt by Chinese authorities to crack down on the illegal sale of blood.

Those found guilty of collecting or supplying blood that causes at least five people to contract AIDS, hepatitis B, hepatitis C or syphilis, or that leads to severe anemia or organ malfunction, could face 10 years to life in prison, said a statement by the Supreme People's Court and the Supreme People's Procuratorate carried by the official Xinhua News Agency.

Unhygienic blood-buying rings were responsible for infecting thousands of people with HIV/AIDS in rural areas of central China, mostly in Henan province, during the mid-1990s. This led to stricter laws on donating blood, making it illegal to sell blood without approval.

But Tuesday's amendment significantly clarifies the range of actions and punishments in China's criminal code, and adds the names of diseases for the first time.

Ni Shouming, the spokesman for the Supreme People's Procuratorate, was quoted Tuesday by the China Daily newspaper as saying blood suppliers who fail to operate according to national standards also face jail terms of less than 10 years.

China milk cover-up started last year
Myanmar government frees 9,000 prisoners
163 dead in Indian monsoon floods

Last year, six people in China's southern Guangdong province were jailed for illegally organizing blood sales and helping people repeatedly sell blood under false names.

Sep 24, 2008

Phase IIa data on TMC435350 in patients with hepatitis C to be presented at AASLD

<http://www.pharmiweb.com>

Medivir today announced that three abstracts related to **TMC435350** have been accepted for poster presentations at the upcoming 59th Annual Meeting of the American Association for Study of Liver Diseases (AASLD) meeting in San Francisco October 31 - November 4. The abstracts for these presentations have been published today and are available on the Hepatology web site (AASLD).

TMC435350 is an investigational protease inhibitor, being developed by Tibotec in partnership with Medivir, for the treatment of hepatitis C virus (HCV). Clinical results from the ongoing phase IIa trial (OPERA-1) will be presented in two posters and a third poster will present preclinical results.

- Safety and antiviral activity of TMC435350 in treatment-naïve genotype 1 HCV-infected patients - M Manns et al.
- Pharmacokinetics of TMC435350, with and without pegIFN and ribavirin, in HCV-infected individuals - G van't Klooster et al.
- Inhibitory activity of TMC435350 on HCV NS3/4A proteases from genotype 1 to 6 - T Lin et al.

The phase IIa proof-of-concept trial (OPERA- 1) is a blinded, randomized and placebo-controlled trial to assess the antiviral activity, safety and pharmacokinetics of once-daily (QD) regimens of TMC435350 in HCV genotype 1 patients. Patients are treated with TMC435350 or placebo once-daily for 4 weeks (28-days) in addition to Standard of Care (SoC) treatment peginterferon alpha-2a (Pegasys®) and ribavirin (Copegus®), which is then continued for another 20 or 44 weeks. Results from Cohort 1, 25mg or 75mg TMC435350 versus placebo, will be reported at AASLD

"These data demonstrate the potent antiviral activity of TMC435350 against genotype-1 HCV", says Lars Adlersson, CEO & President at Medivir. "Based on these clinical and non-clinical studies, we are confident that TMC435350 has the potential to become a valuable addition to available therapy, providing an efficacious treatment with once-daily dosing". OPERA-1 is currently recruiting patients to evaluate higher doses in treatment-naïve HCV patients, as well as those who have not responded or have relapsed on previous SoC treatment.

Safety and antiviral activity of TMC435350 in treatment-naïve genotype 1 HCV-infected patients

50 patients were enrolled in Cohort 1 and treated with either TMC435350 or placebo for 7 days followed by TMC435350 or placebo with SoC for 3 weeks, or TMC435350 or placebo with SoC for 4 weeks. All patients thereafter continued on SoC. The rapid viral response, RVR, defined as HCV RNA less than 10 IU/mL was evaluated at 4 weeks.

TMC435350 at doses of 25mg and 75mg QD demonstrated dose-dependent antiviral activity, both alone and in combination with SoC.

In the 75mg 4-week triple therapy group, 9/9 patients achieved HCV RNA below lower limit of quantification (<25 IU/mL), of whom 8 (of 9) patients achieved undetectable HCV RNA (<10 IU/mL) at day 28 (RVR=89%).

No serious or severe adverse events were related to TMC435350. There were no safety-related treatment discontinuations, and no dose related safety findings. Most common adverse events associated with TMC435350 were nausea, diarrhea and headache.

Pharmacokinetics of TMC435350, with and without pegIFN and ribavirin, in HCV-infected individuals

Pharmacokinetic properties of TMC435350 in healthy volunteers (200mg) and in HCV-infected individuals from two dose groups (25mg and 75mg) in the OPERA-1 trial are presented. For both dosing regimens in HCV infected patients, steady state was readily achieved after three days of once-daily dosing with plasma concentrations essentially proportional to the dose. The plasma trough levels were approximately 10 to 30-fold higher than projected effective levels (EC50 in replicon).

Inhibitory activity of TMC435350 on HCV NS3/4A proteases from genotype 1 to 6

TMC435350 is a potent inhibitor of NS3/4A proteins from genotypes 1 to 6, with IC50 values below 10nM for all HCV NS3/4a enzymes tested with the exception of genotype 3 protease at 100nM. The compound binds non-covalently with fast association and slow dissociation from the protease.

For more information:

http://www.medivir.se/v3/en/ir_media/pr_e_080924.a

Anadys Pharmaceuticals Announces Successful Outcome of ANA598 Healthy Volunteer Study and Finalization of Study Design for Phase Ib Trial in HCV Patients

<http://www.earthtimes.org>

Safety and Pharmacokinetic Results in Healthy Volunteers to be Presented at AASLD SAN DIEGO, Sept. 24

SAN DIEGO, Sept. 24 /PRNewswire-FirstCall/ -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) announced today preliminary results of a Phase I clinical trial of ANA598 in healthy volunteers and finalization of the protocol for a Phase Ib trial of ANA598 in patients chronically infected with hepatitis C virus (HCV). In the healthy volunteer study, ANA598 was well tolerated at all doses analyzed to date and no serious adverse events were reported. All doses achieved plasma drug concentrations predicted to display substantial antiviral activity based on preclinical results. The upcoming Phase Ib study of ANA598 in HCV patients will explore three dose levels -- 200 mg, 400 mg, and 800 mg, each taken twice daily (bid). ANA598 is the company's investigational hepatitis C non-nucleoside polymerase inhibitor.

Phase I Study Results

In the Phase I study in healthy volunteers, ANA598 was administered as capsules at single doses starting at 400 mg. At the 2000 mg dose level, it was administered when fasted and also following a meal. In addition, a separate cohort received two 800 mg doses twelve hours apart. ANA598 was well tolerated at all doses analyzed to date and no serious adverse events were reported, although definitive conclusions regarding product safety and tolerability cannot be made until the results of future clinical trials of longer duration in more patients are known. The pharmacokinetic profile demonstrated sustained plasma levels of ANA598 with a half-life of more than 24 hours, consistent with the potential for once-daily or twice-daily oral dosing. All doses achieved plasma drug concentrations predicted to display substantial antiviral activity based on preclinical results. Additionally, absorption was enhanced when ANA598 was taken with food, indicating that it should not be necessary to take ANA598 on an empty stomach in order to achieve desired plasma drug levels.

Additional detail from the Phase I study, including full PK results from the twice-daily 800 mg cohort, will be presented at the 59th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), to be held in San Francisco, California, October 31 - November 4, 2008. Abstracts can be viewed at the AASLD website at <http://www.aasld.org>.

ANA598 Program Update

Anadys is now finalizing preparations to begin a Phase Ib trial of ANA598 in HCV patients early in the fourth quarter. The study will be conducted at several sites in the United States. The regulatory review necessary to initiate the study has been completed. In the Phase Ib monotherapy study, naive genotype 1 patients will receive ANA598 over three days, at doses of 200 mg bid, 400 mg bid or 800 mg bid. Ten patients are planned to be enrolled in each of the three cohorts, eight on active treatment and two on placebo. Anadys expects to have viral load data from all three cohorts in the first quarter of 2009. Anadys may elect to explore other dose levels of ANA598 and/or once-daily dosing in this study, depending on data from the first three cohorts.

In September, Anadys initiated long-term chronic toxicology studies of ANA598. As communicated in April of this year, Anadys made the strategic decision to accelerate into 2008 certain non-clinical activities for the ANA598 program, including the initiation of these long-term toxicology studies and the manufacture of additional drug substance. If ANA598 is successful in early stage clinical trials, it is anticipated that the acceleration of these non-clinical activities into 2008 will enable a more rapid and continuous development path into Phase II studies during 2009.

ANA598 Data to be Presented at AASLD Meeting

Anadys will present data on ANA598 during three poster sessions at the 59th Annual Meeting of the AASLD, to be held in San Francisco, California, October 31 - November 4, 2008. The full abstracts, which are summarized below, can be viewed at the AASLD website at <http://www.aasld.org>.

Anadys will present a late-breaker poster at a session beginning at 8:00 a.m. PST on Monday, November 3.

- The poster, titled "Results of a Phase I Safety, Tolerability and Pharmacokinetic Study of ANA598, a Non-Nucleoside NS5B Polymerase Inhibitor, in Healthy Volunteers", will present data from the first clinical study of ANA598.

Two additional posters will be presented on Tuesday, November 4, 2008:

- In a poster titled "Antiviral Efficacy of the HCV RNA Polymerase Inhibitor ANA598 in the Chimpanzee Model of HCV Infection", Anadys will present data showing that ANA598 exhibits a substantial antiviral effect against both genotype 1a and 1b virus in HCV-infected chimpanzees. ANA598 was given as single and multiple oral doses and was well-tolerated in the study.
- In a poster titled "In Vitro Studies Demonstrate that Combinations of Antiviral Agents that Include HCV Polymerase Inhibitor ANA598 have the Potential to Overcome Viral Resistance", Anadys will present the results of in vitro studies that show ANA598 to be strongly synergistic with interferon-alpha. These studies also show that ANA598 retains activity against mutants known to confer resistance to other classes of direct antivirals, including protease inhibitors, nucleoside inhibitors and non-nucleosides that bind at the thumb site. In addition, genotypic mutations resistant to ANA598 will be presented and shown to be fully susceptible to interferon-alpha, a representative protease inhibitor and a representative nucleoside polymerase inhibitor.

About ANA598

Preclinical evaluation of ANA598 was completed in the first quarter of 2008, leading to submission of an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA), subsequent allowance of the IND by the FDA and initiation of clinical investigation in the second quarter of 2008. In the preclinical program, ANA598 was well tolerated at all doses tested in 28-day GLP toxicology studies. Furthermore, ANA598 was shown to be active in a primate model of chronic HCV infection, leading to a greater than 2 log viral load decline in each of two genotype 1b infected animals. Anadys has previously reported data demonstrating that ANA598 retains undiminished activity against a number of HCV variants resistant to other direct antivirals currently in development.

Clinical Need and Market Opportunity in HCV Infection

Chronic HCV infection is a serious public health concern affecting approximately 3.2 million people in the United States and approximately 170 million people worldwide. HCV causes inflammation of the liver, which can lead to fibrosis and cirrhosis, and may ultimately lead to liver failure and/or liver cancer if not successfully treated. Cirrhosis of the liver resulting from chronic HCV infection is the leading indication for liver transplantation in the U.S. Due to the asymptomatic nature of HCV infection, it often goes undetected for up to 20 years following initial infection. Each year, 8,000 to 10,000 people in the U.S. die from complications of HCV.

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

About Anadys

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

SOURCE Anadys Pharmaceuticals, Inc.

Telaprevir Presentations at the 59th AASLD Meeting to Feature SVR Data in Treatment-Naïve and Treatment-Failure Genotype 1 HCV Patients, and Clinical Data Exploring Twice-Daily Dosing Regimens

<http://www.marketwatch.com>

CAMBRIDGE, Mass., Sep 24, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated today announced that key data on sustained viral response (SVR) rates in both treatment-naïve and treatment-failure genotype 1 hepatitis C (HCV) patients who received telaprevir-based treatment regimens will be presented at the 59th Annual Meeting of the American Association for the Study of Liver Disease (AASLD), October 31 -- November 4, 2008 in San Francisco. In addition, week 4 and week 12 data from the C208 study exploring a twice-daily telaprevir dosing regimen in 160 genotype 1 HCV patients will be presented. A total of six abstracts related to Vertex's HCV protease inhibitor telaprevir clinical program were accepted for presentation. The abstracts are being published today and will be available online at

the AASLD website (www.aasld.org). Vertex is developing telaprevir in collaboration with Tibotec.

Telaprevir-Based Therapy in Treatment-Failure HCV Patients:

PROVE 3 Interim Analysis

- "A Phase 2b Study of Telaprevir with Peginterferon-Alfa-2a and Ribavirin in Hepatitis C Genotype 1 Null and Partial Responders and Relapsers Following a Prior Course of Peginterferon-Alfa-2a/b and Ribavirin Therapy: PROVE 3 Interim Results" will be presented in an oral session on Tuesday, November 4 at 11:30 a.m. PST. The authors of the study are J. G. McHutchison, M. L. Shiffman, N. Terrault, M. P. Manns, A.M. Di Bisceglie, I. M. Jacobson, N. H. Afdhal, E. J. Heathcote, S. Zeuzem, H. W. Reesink, S. George, N. Adda and A. J. Muir.

Study 107 Interim Analysis

- "A Study of Telaprevir Combined with Peginterferon-Alfa-2a and Ribavirin in Subjects with Well-Documented Non-Response or Relapse after Previous Peginterferon-Alfa-2a and Ribavirin Treatment: Interim Analysis" will be presented at a poster session on Tuesday, November 4 from 8:00 a.m. to 12:30 p.m. PST. The authors of the study are M. L. Shiffman, T. Berg, F. F. Poordad, J. Bronowicki, A. J. Muir, S. C. Gordon, S. George, N. Adda and J. G. McHutchison.

Telaprevir-Based Therapy in Treatment-Naïve HCV Patients

PROVE 2 Final Results

- "Telaprevir in Combination with Peginterferon-Alfa-2a with or without Ribavirin in the Treatment of Chronic Hepatitis C: Final Results of the PROVE 2 Study" will be presented in an oral session on Tuesday, November 4 at 9:30 a.m. PST. The authors of the study are S. Zeuzem, C. Hezode, P. Ferenci, G. M. Dusheiko, K. Alves, L. Bengtsson, S. Gharakhanian, R. Kauffman, J. Alam and J. Pawlotsky.

C208 Study Interim Analysis -- Twice-Daily Telaprevir Exploration

- "Phase 2 Study of Telaprevir Administered q8h or q12h with Peginterferon-Alfa-2a or -Alfa-2b and Ribavirin in Treatment-Naïve Subjects with Genotype 1 Hepatitis C: Week 4 Interim Results" will be presented at a poster session on Tuesday, November 4 from 8:00 a.m. to 12:30 p.m. PST. The authors of the study are X. Forns, P. Marcellin, T. Goeser, P. Ferenci, F. Nevens, G. Carosi, J. P. Drenth, K. De Backer, R. van Heeswijk, T. J. Vangeneugden, G. Picchio and M. Beumont-Mauviel.

Additional Telaprevir Abstracts at AASLD

- "Viral Responses in African-Americans, Latinos and Caucasians in the US Phase 2 Study (PROVE 1) of Telaprevir with Peginterferon Alfa-2a and Ribavirin in Treatment-Naïve Genotype 1-infected Subjects with Hepatitis C" will be presented at a poster session on Tuesday, November 4 from 8:00 a.m. to 12:30 p.m. PST. The authors of the study are A. J. Muir, E. J. Lawitz, J. G. McHutchison, S. C. Gordon, I. M. Jacobson, B. Adiwijaya, L. Bengtsson, L. McNair and M. Rodriguez-Torres.
- "No Compensatory Fitness Mutations Selected in NS3/4A Protease Cleavage Sites During Treatment with Telaprevir, Peg-IFN-Alfa-2a, and Ribavirin in Phase II Studies of Treatment-

NaAve HCV Genotype 1-Infected Patients" will be presented at a poster session on Tuesday, November 4 from 8:00 a.m. to 12:30 p.m. PST. The authors of the study are E. Z. Zhang, D. J. Bartels, J. Sullivan, M. Marcial, J. Dorrian, A. Tigges, A. D. Kwong and T. L. Kieffer.

About Telaprevir

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 in Phase 3 clinical trials in treatment-naAve and treatment-failure patients.

About Vertex

Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration with major pharmaceutical companies. Vertex's product pipeline is focused on viral diseases, inflammation, autoimmune diseases, cancer, pain and cystic fibrosis. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

Sep 25, 2008

What Is The Energy Consuming Style In Chronic Severe Hepatitis B Patient Normality?

<http://www.medicalnewstoday.com>

The liver plays a pivotal role in fuel and energy metabolism. Many studies have shown that patients with liver cirrhosis have nutrient and energy metabolism imbalances, which lead to malnutrition and can seriously affect their prognosis. However, the characteristics of the fuel and energy metabolism in patients with chronic severe hepatitis are not clear.

A research article published in the *World Journal of Gastroenterology* addresses this question. The research team led by Professor Hui-Guo Ding investigated REE and oxidation rates of glucose, fat, and protein in chronic severe hepatitis B patients.

One hundred patients with liver diseases were categorized into 3 groups: 16 in the acute hepatitis group; 56 in the chronic severe hepatitis group; and 28 in the cirrhosis group. The REE and the oxidation rates of glucose, fat, and protein were assessed by indirect heat measurement.

They found that REE of chronic severe hepatitis patients was not significantly different from that of acute hepatitis and cirrhosis patients, who do not have increased energy metabolism. The REE per kg weight was similar in the chronic severe hepatitis group to that in the cirrhosis group, and both were lower than that in the acute hepatitis group ($P=0.014$). The RQ of the chronic severe hepatitis group (0.84 ± 0.06) was significantly lower than that of the acute hepatitis and cirrhosis groups ($P=0.001$). The proportion of energy supplied by the three major substrates (carbohydrate, fat, and protein) differed among the groups. Protein oxidation rates were not significantly different among the groups; they ranged from 21.0% to 22.2%. The carbohydrate oxidation rate of the severe hepatitis group (39.2%) was significantly lower than that of the acute

hepatitis group and the cirrhosis group ($P < 0.05$). The fat oxidation rate of the severe hepatitis group (39.8%) was significantly higher than that of the acute hepatitis group and the cirrhosis group ($P < 0.05$).

The energy metabolism was significantly improved when they recovery from severe stage. It is very interesting that 4 of these patients had been given growth hormone (4.5 IU/day for 2 wk), the glucose oxidation rate increased from 41.7% to 60.1%, while the fat oxidation rate decreased from 26.3% to 7.6%.

In their conclusion, the glucose oxidation rate is significantly decreased, and a high proportion of energy is provided by fat in chronic severe hepatitis. The measurement of REE and the oxidation rates of fat, glucose and protein substrates can be used to determine the optimal nutritive support therapy for severe liver disease patients.

Article adapted by Medical News Today from original press release.

Reference:

Fan CL, Wu YJ, Duan ZP, Zhang B, Dong PL, Ding HG. Resting energy expenditure and glucose, protein and fat oxidation in severe chronic virus hepatitis B patients. *World J Gastroenterol* 2008; 14(27): 4365-6369 <http://www.wjgnet.com/1007-9327/14/4365.asp>

How to select anti-hepatitis B virus agents for drug-resistance patients?

<http://www.eurekalert.org>

HBV infection may lead to acute liver disease, chronic active hepatitis, liver cirrhosis, and hepatocellular carcinoma. Over 350 million people worldwide are estimated to be infected chronically by HBV and are therefore at risk of liver failure, cirrhosis, or hepatocellular carcinoma. The principal treatment for chronic hepatitis B (CHB) involves the use of interferon alpha (IFN- α) or nucleoside analogs. In vitro analysis of clinical HBV isolates is currently difficult for lacking of HBV cellular culture model

A research article to be published on 14 June 2008, in the *World Journal of Gastroenterology* addresses this question. The research team led by Prof. Yin-Ping Lu from Union Hospital of Tongji Medical College reported a useful strategy to select anti-HBV agents for drug-resistance patients. The full-length HBV genomic DNA from chronic hepatitis B patients were amplified by polymerase chain reaction (PCR). The amplified HBV DNA fragments were inserted into an universal HBV expression vector respectively. The recombinant plasmids containing 1.1 copies of HBV genome were transiently transfected into Huh7 cells and antiviral susceptibility of lamivudine and adefovir were analyzed in vitro model system. Furthermore, the antiviral susceptibility of adefovir in vivo were observed subsequently.

Eight clinical HBV isolates from different individual with lamivudine-resistance were cloned into HBV expression vector, and recombinant plasmids were transiently transfected into Huh7 cells. The results indicated that HBV genome of clinical HBV isolates could effectively replicate and be expressed in Huh7 cells. Adefovir but not lamivudine inhibited HBV replication both in vitro and in vivo.

The novel method described in this article enables rapidly selecting of anti-HBV agents in clinic and will be useful in future studies of antiviral therapy for chronic hepatitis B.

Reference:

Lu YP, Guo T, Wang BJ, Dong JH, Zhu JF, Liu Z, Lu MJ, Yang DL. Replication of clinical HBV isolate and its application for selecting antiviral agents for chronic hepatitis B patients. World J Gastroenterol 2008; 14(22):3490-3496
<http://www.wjgnet.com/1007-9327/14/3490.asp>

GlobeImmune Announces Late-Breaker Presentation of Interim Efficacy and Safety Data for GI-5005 at AASLD 2008 Meeting

<http://www.marketwatch.com>

LOUISVILLE, CO, Sep 24, 2008 (MARKET WIRE via COMTEX) -- GlobeImmune, Inc. today announced that a late breaking abstract related to **GI-5005**, its investigational hepatitis C virus (HCV) product candidate, has been accepted for presentation at the 59th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which will take place Oct. 31 through Nov. 4, 2008, in San Francisco.

The abstract, titled "GI-5005 Immunotherapy Plus Peg-IFN/Ribavirin In Genotype 1 Chronic Hepatitis C Patients Compared to Peg-IFN/Ribavirin Alone in Naive and Non-Responder Patients; Preliminary RVR and Viral Kinetic Analysis from the GI-5005-02 Phase 2 Study," was published online today by the AASLD.

At the AASLD meeting, GlobeImmune will present interim data from a Phase 2 clinical study investigating the efficacy and safety of GI-5005 plus peg-interferon (peg-IFN) and ribavirin, the current standard of care (SOC), in patients with genotype 1 chronic HCV infection.

Dr. John G. McHutchison of Duke University is the lead author of the abstract that will be presented as part of a late breaking poster session beginning at 8 a.m. PDT on Monday, Nov. 3, 2008. The analysis will include rapid virologic response (RVR) rates and viral kinetic analyses for patients who have completed the first four weeks of triple therapy, as well as SOC patients in the control arm of the study.

GI-5005 is an immunotherapy product candidate that contains conserved HCV proteins and is designed to generate HCV specific T-cell responses in both the pre-clinical and clinical setting.

About GlobeImmune, Inc.

GlobeImmune is a private, Colorado-based company developing active immunotherapies called Tarmogens(R) for the treatment of cancer and infectious diseases. The Company's lead product candidate, GI-5005, is a Tarmogen being developed for the treatment of chronic hepatitis C infection that has completed a Phase 1b clinical trial. GI-5005 is designed to complement both the current standard of care and emerging novel therapies for hepatitis C infection. The Company has fully enrolled a 140-patient randomized, controlled Phase 2 study of GI-5005 in combination with standard of care for chronic hepatitis C infection. The Company's lead oncology program, GI-4000, targets mutated versions of the Ras oncoprotein and is designed to be a treatment for cancers of the lung and gastrointestinal tract that contain mutated Ras. A randomized, placebo-

controlled Phase 2 trial in patients with resected pancreas cancer in combination with adjuvant gemcitabine is ongoing.

For additional information, please visit the company's Web site at www.globeimmune.com.

SOURCE: GlobeImmune, Inc.

Duke NCRC researchers studying

<http://www.salisburypost.com>

By Emily Ford

eford@salisburypost.com

KANNAPOLIS — Researchers for Duke University's MURDOCK Study want to understand why 50 percent of people treated for Hepatitis C never get better.

In the next six months, they could share some preliminary research results with the world.

MURDOCK Study investigators working on the Hepatitis C project are beginning to see genetic differences in the receptors, or entry points, for the virus, Dr. John McHutchison said Tuesday at N.C. Research Campus.

The groundbreaking study will focus on four diseases including Hepatitis C, a global killer that will become a growing problem in the United States as those infected in the 1960s, '70s and '80s begin to develop liver disease.

Injection drug use and contaminated blood transfusions before 1992 infected an estimated 4 million to 5 million Americans with the Hepatitis C virus. Many of them don't even know it yet.

"Liver disease will increase dramatically over the next two decades," McHutchison, a MURDOCK Study lead investigator, said at a seminar in the Core Laboratory Building.

There is no vaccine for Hepatitis C, and only a blood test can detect it. Treatment with drugs cures the disease for only half of those who undergo the grueling, yearlong therapy.

Having Hepatitis C is like "living with a time bomb," McHutchison said. "No one can predict what will happen."

Researchers at Duke's campus in Durham and the Core Lab in Kannapolis want to do just that — predict which people will develop the infection and learn why some patients respond to treatment, while others stay sick or die.

That will take years. But even before the Core Lab officially opens Oct. 20, MURDOCK Study scientists have made progress toward their first goal, discovering the profile of a patient who will or will not respond to therapy.

When Research Campus founder David Murdock gave Duke \$35 million last year to launch the study, scientists used some of the money to begin running new tests on old biological samples stored at Duke from patients with liver disease.

Murdock's gift created a "good perfect storm," said Victoria Christian, chief operating officer for the MURDOCK Study.

It provided funding to begin measuring millions of proteins and genes with new technologies called proteomics and genomics, which could be the key to determining the genetic cause of disease.

Soon, the bulk of Duke's MURDOCK Study research will move to the Core Lab and Duke's own building, which is still in the planning stages.

Researchers will continue using old samples during the first phase of the MURDOCK Study. Later, they will test their hypotheses using samples collected from 50,000 Kannapolis and Cabarrus County residents.

Several people who attended Tuesday's seminar spoke up and said they were either infected with Hepatitis C or they have a family member with the virus.

"It was quite a powerful interchange," Christian said.

If those people enroll in the study registry, which will begin this fall, they could participate in more specific research on Hepatitis C and play a valuable role in understanding the disease, Christian said.

Successful construction of eukaryotic plasmids containing HBV C genotype

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

HBV infection remains a major health problem in the world. Several data have revealed that lamivudine can efficiently promote the treatment of hepatitis B. However, a long-term treatment of lamivudine leads to the emergence of lamivudine-resistant mutants (YMDD mutants), which hampers the anti-HBV therapy. Therefore, researches related to HBV lamivudine-resistant mechanism has been of great significance. Up to date, many researches using eukaryotic plasmids containing either one type of HBV YMDD mutant or wild-type strains, without specification of HBV genotype, were reported. However, serial plasmids containing a specific HBV genotype, such as genotype C, and lamivudine-resistant sequences, which will allow systematic studies on the combined effects of HBV genotype together with lamivudine-resistant mutations, have not been reported.

A research article to be published on 21 June 2008, in the World Journal of Gastroenterology addresses this question. The research team led by Prof. Gu Hongxi from Department of Microbiology of Harbin Medical University successfully constructed the eukaryotic expression plasmids pcDNA3.1(+)-HBV/C-YMDD, pcDNA3.1(+)-HBV/C-YVDD, and pcDNA3.1(+)-HBV/C-YIDD. After being transfected into HepG2 cells, these plasmids could efficiently

express viral DNA and antigens of HBV genotype C wild-types, YVDD, and YIDD mutation, respectively. These results provide an experimental basis for further in vitro studies on HBV lamivudine-resistant mutants.

The successful construction of the 3 eukaryotic plasmids, pcDNA3.1(+)-HBV/C-YMDD, pcDNA3.1(+)-HBV/C-YVDD, and pcDNA3.1(+)-HBV/C-YIDD, provides an experimental basis for the establishment of stable expression system of HBV genotype C lamivudine-resistant mutants. The results may contribute to further in vitro antiviral studies of HBV genotype C lamivudine-resistant mutants, such as establishing a stable expression system of HBV genotype C lamivudine-resistant mutants, studying on the mechanism of HBV lamivudine-resistance.

Reference:

Xu WZ, Fang Y, Li D, Wang Y, Shang QL, Li GQ, Teng X, Gu HX. Construction and expression of eukaryotic plasmids containing lamivudine-resistant or wild-type stains of HBV C genotype. *World J Gastroenterol* 2008;14 (23): 3733-3738
<http://www.wjgnet.com/1007-9327/14/3733.asp>

Sep 26 2008

Presidential Candidates Present Their Healthcare Reform Plans in NEJM

www.medscape.com

Neil Osterweil

September 26, 2008 — With the nation's attention riveted on Wall Street, government bailouts, and housing foreclosures, another issue of prime concern to Americans in this election year has been shoved out of the spotlight: Sen. Barack Obama's and Sen. John McCain's positions on healthcare reform.

The *New England Journal of Medicine* invited both the Democratic and Republican candidates for president of the United States to outline their plans for healthcare reform, with commentary on each provided by observers from the opposite end of the political spectrum. Outlines of the candidates' plans and the critiques were published online September 24 and will appear in the October 9 (plan outlines) and October 16 (critiques) print issues of the journal.

There isn't much that the candidates agree on in other areas of public policy. But in side-by-side columns with color-coded headings — blue for Sen. Obama and red for Sen. McCain — the senators lay out their strategies for providing universal access to affordable, high-quality care.

However, their strategies outline fundamental philosophical differences, with Sen. Obama embracing a more public solution and Sen. McCain endorsing a more market-based approach.

The Obama Plan

Sen. Obama, who favors a mix of public and private participation, outlines 3 broad healthcare reform goals:

- Equal access to high-quality, affordable health care for all Americans.

- Elimination of wasteful spending, including "layers of bureaucracy that serve no purpose, duplicative tests and procedures that are performed because the right information is not readily available, and doctors providing unnecessary care for fear of being sued."
- Emphasis on disease prevention and health maintenance.

According to Sen. Obama, patients who like their insurance will be able to retain it with no changes, except for lower costs. Uninsured or underinsured patients would be offered a choice of affordable plans, and he calls for establishment of a national health-insurance exchange for small businesses or people without employment-based insurance; the plans would offer policies at rates similar to those offered through large companies, although Sen. Obama does not specify how this would be achieved.

"To promote competition among insurers, we will also give patients a new public-plan option, providing the same coverage that is offered to members of Congress and their families," the Democratic candidate writes.

Sen. Obama's plan also calls for:

- Mandatory acceptance of enrollees by insurers without regard to medical history.
- Tax credits for families to increase affordability.
- Expansion of Medicaid and the State Children's Health Insurance Program (S-CHIP) to cover all children without private coverage.

Sen. Obama says that the expanded programs will be paid through elimination of waste and through repeal of the Bush administration tax cuts for Americans with the highest incomes. He notes that he opposes taxes on employer-based health insurance.

Reimbursement, Medical Liability Changes

"We also need to change the way we reimburse for patient care," Sen. Obama writes. "We should start paying adequately for care coordination, case management, and innovative care-delivery models, such as team-based care and electronic communication. Doctors should be paid fairly by private insurers and by Medicare. Payment reform should improve patient outcomes and should lower overall costs by removing incentives for unnecessary care and rewarding the right care, provided at the right time, for the right reasons"

Sen. Obama states that his administration will offer incentives for physicians in training to enter primary care, and he emphasizes renewed support for biomedical research. He also proposes to reduce malpractice insurance burden through information systems, decision support technology, and patient-safety initiatives aimed at reducing medical errors.

"I will also support legislation dictating that if you practice care in line with your medical societies' recommendations, you cannot be sued," he writes.

"Too Audacious to Be Believed"

In an editorial critical of the Obama plan, Joseph R. Antos, PhD, a scholar in healthcare and retirement policy at the American Enterprise Institute, a conservative think-tank in Washington, DC, says that the Obama plan is "too audacious to be believed."

"The Obama plan offers a host of policy proposals that, in the main, address the symptoms but not the underlying disease that afflicts the health care system," Dr. Antos writes. "We surely could use some symptomatic relief. However, failing to address the perverse incentives that drive health care spending

inexorably upward, making insurance unaffordable for millions and shaping (or misshaping) the practice of medicine, will leave us worse off than we are today."

The "perverse incentives" Dr. Antos refers to include a "play or pay" option, similar to that currently in place in Massachusetts, under which employers that do not provide health insurance coverage pay a per-worker surcharge that is used to finance a publicly funded healthcare system.

"A play-or-pay policy probably would not be effective in expanding employer-sponsored insurance," Dr. Antos writes. "Employers who already offer generous health benefits would not have to change their compensation structure. Other employers would choose to 'pay' rather than 'play' unless the new tax were more expensive than the cost of paying the mandated amount for insurance, which is politically implausible."

Dr. Antos also claims that the non-group insurance plans offered to uninsured families under Sen. Obama's plan must of necessity either offer a wide range of benefits and be costly or offer more narrow but less costly basic plans with high out-of-pocket costs.

"A generous plan requires premiums that would be unaffordable to many of the uninsured unless there was also a generous subsidy from taxpayers," he writes. "A more basic plan would have more affordable premiums, but beneficiaries would face higher out-of-pocket costs if they became seriously ill. Lower premiums and skimpier benefits are not what the Democratic political base thinks it has been offered."

The author is also critical of the Democrat's proposed health insurance exchange, saying that it would limit the market-based competition, and adds that Sen. Obama's plan to regulate health insurers more closely "substantially increases the risk of government failure and regulatory gridlock."

The McCain Plan

Sen. McCain favors a market-driven, privately funded approach to healthcare, although he too emphasizes basic tenets of reform, including:

- Access to high-quality care
- Choice of insurance coverage
- Affordability
- Portability

"But the road to reform does not lead through Washington and a hugely expensive, bureaucratic, government-controlled system," he writes.

Sen. McCain calls for moving Medicare toward a system that favors coordinated care and "higher quality care" for seniors, but does not specify how this would be accomplished.

The Arizona senator supports a greater emphasis on health maintenance, screening, prevention, and early intervention.

"We need to create a next generation of efforts to prevent chronic disease, early intervention programs, new treatment models, and public health infrastructure," he writes. "We need to use technology to share information on 'best practices' in health care so that every physician is up to date. We need to adopt new treatment programs and financial incentives to promote healthy habits among Americans with the most common conditions, such as diabetes and obesity, in order to improve their quality of life and reduce the cost of their treatment."

Tax Credits, Tort Reform

Sen. McCain's plan calls for dropping the exclusion of the value of health insurance from an employee's taxable compensation, and replacing it with a refundable tax credit of \$2500 for individuals or up to \$5000 for families.

"For the first time the credit will provide help to people who are shut out of the job-based insurance system; they will be able to choose an insurer or other health care arrangement, and the credit will be sent straight to the plan they pick in order to help pay their premiums," he writes. "An essential benefit of this reform is that it will help to change the whole dynamic of the current health care system by putting individuals and families back in charge and forcing insurance companies to respond with better service at lower cost."

Sen. McCain favors a state-based rather than national plan for ensuring access to care for people with preexisting medical conditions and "additional help for low-income individuals."

Sen. McCain points to his record of advocacy for medical liability reform legislation, emphasizing that it must be a central component of healthcare reform. He does not offer specifics on what tort reform under a McCain administration would look like.

"Health care reform is too important an issue for one person or one party to tackle alone, and I have a record of working across party lines to tackle big challenges and change the way Washington works. By starting with putting doctors and patients back at the center of health care decisions, we can reform the U.S. system in a way that protects the quality of care while making it affordable and accessible to all," he writes.

"The McCain Plan for Health Insecurity"

In his critique of the McCain healthcare reform plan, David Blumenthal, MD, MPP, director of the Institute for Health Policy at Massachusetts General Hospital in Boston, and an unpaid advisor to the Obama campaign, writes that "the McCain proposal violates the bedrock principle that major health policy reforms should first do no harm. It would risk the viability of employer-sponsored insurance and the welfare of chronically ill Americans in pell-mell pursuit of a radical vision of consumer-driven health care."

Sen. McCain's plan, he says, would increase patient out-of-pocket costs and reduce the role of insurance in healthcare. He notes that three fifths of Americans currently rely on employer-sponsored healthcare, and that Sen. McCain's plan would "increase reliance on unregulated individual insurance markets (which are notoriously inefficient), and leave the number of uninsured Americans virtually unchanged."

Dr. Blumenthal charges that by ending the exemption from federal income tax for employer-sponsored insurance, employers would likely drop the plans.

"Over the years, multiple studies have shown that as the tax benefit to employees of receiving employer-sponsored insurance declines, employers are less likely to offer it," he writes. "On the basis of these studies, economists project that 10 million to 28 million of the 160 million Americans with employer-sponsored insurance will lose it as a result."

The plan is also likely to encourage other employers to reduce benefits, thereby increasing employee costs, and would drive the newly uninsured into the more costly non-group insurance market, where administrative costs make up 30% to 50% of premiums compared with 12% to 15% of costs in employer-sponsored large group plans.

Dr. Blumenthal is also skeptical about Sen. McCain's proposal for establishment of association health plans (AHPs) that would allow groups of consumers to buy health insurance for their members.

"By joining such plans, individuals will presumably enjoy the protections that large groups, including employer pools, offer their members. However, the required AHPs don't exist now. If they did, they would be tempted to cherry-pick healthy members just as insurance companies do. Voluntary associations of the sick and healthy do not naturally occur, and there is a good reason why," Dr. Blumenthal writes.

The author also states that deregulation of private insurance markets, as called for by the McCain plan, would eliminate some state mandates that insurance companies provide policies for all who wish to buy them, thereby allowing the companies to "cherry pick" the healthier subscribers while denying coverage to higher insurance risks.

Although Sen. McCain calls for establishment of state-run high-risk insurance pools, such pools, established in 35 states, enroll fewer than 200,000 people, Dr. Blumenthal noted.

"The reason is that states are unwilling or unable to subsidize adequately the extremely high premiums that pools charge the chronically ill," he writes. "McCain has talked vaguely of providing additional federal funds (in the range of \$7 billion to \$10 billion) to help states out, but he has not detailed this part of his plan. In any case, it raises a more fundamental question: What are the long-range consequences of segregating the sickest Americans into a predominantly state-run high-risk insurance system, especially in regions that have been notoriously ungenerous toward vulnerable populations?"

The full text of the plans and critiques are available online at www.nejm.org. Also on the site is a video of a presidential campaign healthcare forum presented at the Harvard School of Public Health in Boston in September.

Health spending may have to slow as economy stalls

www.reuters.com

By Ben Hirschler

LONDON (Reuters) - Spending on healthcare may have to slow as Western economies stall, bringing to an end a period in which expenditure has far outstripped growth in GDP, a leading health policy expert said on Friday.

Between 1990 and 2005, health spending in the industrialized world rose in real terms almost twice as fast as gross domestic product (GDP), at 4.5 percent compared with 2.5 percent.

Nick Bosanquet, a professor of health policy at Imperial College, London, believes this is unsustainable in an era of lower growth.

Capping healthcare spending at around the current level of 8-9 percent of GDP -- the typical rate for most developed countries apart from the United States -- would force healthcare providers to use their existing vast resources more efficiently, he wrote in the British Medical Journal.

"There will be no incentive to invest in a new kind of health service while the easy option of continued growth in high spending in the old one remains," he said.

An aging population, new technologies and better drugs have all combined to push up the cost of medical care around the world.

The result has been runaway healthcare bills for governments and insurers, who are now pushing back by demanding better deals from suppliers of products and services.

Today's market is characterized by intense competition in large areas of conventional medicine, which is hitting drug industry profits, although those firms specializing in biotech treatments for cancer and other complex diseases are still able to command sky-high prices.

In the longer term, health spending may well rise as a share of GDP but Bosanquet said the challenge for the next five years was to redesign services for the future -- and for that to happen there had to be strong economic incentives at all points in the health system.

Not everyone agrees, however.

Writing in the same journal, Werner Christie -- a former health minister of oil-rich Norway -- said health spending should reflect medical needs, "not unstable economic trends."

He argued that healthcare was not simply a cost, given that institutions involved in providing healthcare were among the biggest enterprises and employers in any community.

"We therefore need to substantially improve our assessment of healthcare's GDP and may then find that current and even increased investment in health is quite profitable," he said.

(Editing by Andy Bruce)

Cancer Clinic Causes Worst Hepatitis Outbreak in US History

<http://newsblaze.com>

To date, nearly 90 cases of hepatitis C may be linked to the Las Vegas Endoscopy Center of Southern Nevada. The clinic notified 50,000 patients of possible exposure to the virus, and if more tests continue to come back positive, this case will surpass the damages of a similar disaster that occurred at a Nebraska oncology clinic in 2000.

In the small, farming community of Fremont, Nebraska, townspeople welcomed Dr. Tahir Javed, an acclaimed doctor as the first full-time oncologist at the new, local cancer treatment center. But the fanfare soon turned into a nightmare when 857 cancer patients were subjected to a deadly, blood-borne virus passed on by reused, contaminated syringes during chemotherapy treatments.

In all, ninety-nine of these patients were diagnosed with the hepatitis C virus, making this incident the largest healthcare-transmission outbreak in United States history, to date.

While undergoing breast cancer treatment at the Fremont clinic, Evelyn McKnight contracted the virus. Her new book, *A Never Event* (a term used to describe a preventable healthcare tragedy) chronicles the true account of her experience, as well as the stories of several other victims of the outbreak.

"If you plan on receiving healthcare in the future, this book is a must-read," says Ms. McKnight. "The factors that caused my tragedy still occur in healthcare facilities throughout the country."

Ms. McKnight, along with co-author Travis Bennington, an attorney who represented nineteen of the outbreak's victims, and in conjunction with Dr. Thomas McKnight, has created the advocacy organization HONORreform. The non-profit foundation has received enormous attention from CBS Evening News, CNN's America Morning, USA Today, The Associated Press and Newsday.

"We started HONORreform to promote patient safety, justice and compassion," says Ms. McKnight. "As soon as I knew I was infected because of medical malpractice, I promised that any monetary award I would gain from this horrible experience would be used to help others."

While *A Never Event* reveals the story of the Nebraska hepatitis C outbreak there have been 70,000 patients in cities throughout America that have received letters notifying them of possible exposure to blood-borne diseases. These facts are startling:

- In the United States, there have been fourteen documented outbreaks of hepatitis since 1999. Among the affected are forty-two patients in New York City and 102 (some of which are cases of hepatitis B) in Oklahoma
- Healthcare providers have reused syringes and other equipment to save time and money, so they can cram more procedures (and profits) into a day's schedule.
- During the discovery of the Nebraska outbreak, Dr. Tahir Javed fled the country to the Middle East.
- Every person who receives healthcare is potentially at risk of suffering a similar fate, particularly if they receive injections of any kind.

"I went to the doctor to be healed, and I came away with a life-threatening illness," says Ms. McKnight. "There is a huge sense of betrayal."

"History untold is history repeated," says co-author Travis Bennington. "By telling the story of the Nebraska hepatitis C tragedy, we hope future communities will be spared such pain and suffering."

Please feel free to contact the authors directly through their Website: www.HonoReform.org .

Court sides with firefighter in city suit

<http://www.orlandosentinel.com>

Mark Schlueb | Sentinel Staff Writer

The Florida Supreme Court sided with a former Orlando firefighter in a long-running medical claim against the city, but the man didn't live long enough to see the victory.

In 2001, Bob Flamily drew national attention with his claim that Orlando officials had failed to share years of his own medical test results showing symptoms of hepatitis C. The case prompted other Orlando firefighters to check their own files at a city-run employee clinic, find undiscovered ailments and join a lawsuit against the city. The suit ultimately failed, but the city changed the way it provides medical care for its firefighters.

Flamily's case started when he took medical retirement from the Orlando Fire Department in 1996 due to a heart condition and accepted a worker's compensation settlement of about \$100,000. But he came to believe city officials had misled him about how much he should have received.

The case grew when Flamily's attorney, Geoff Bichler, looked at years of test results from his client's annual physicals. They showed elevated liver enzyme levels that Flamily said he was never told about. By the time he sought further tests, it was too late: He was in the final, terminal stages of liver disease from hepatitis C.

For years, firefighters had been pushing the state to include blood-borne diseases such as hepatitis on a list of medical conditions that are automatically presumed to be work-related. Flamily said he must have been exposed to hepatitis on the job. City lawyers argued otherwise.

A judge issued a split decision in 2004. He agreed Flamily should have received a bigger settlement for his heart ailment. But he said the former firefighter couldn't prove his hepatitis was work-related.

The 1st District Court of Appeal sided with the city. In June 2007, Flamily's lawyer argued before the Supreme Court, which Thursday reversed the appellate ruling, in essence saying Flamily should get more.

Perhaps more significant, Bichler said, is that the Supreme Court also told the appellate court to consider whether the city can deny responsibility for Flamily's hepatitis because it did not keep his medical records. If the appellate court sides with Flamily, it could affect medical claims by firefighters all over the state.

Flamily died in 2006. City officials said they aren't sure of their next step.

REVIEW: Will Self, Southport Arts Centre

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

By Kathryn Carr

“I’VE got sandwiches for you all...” said author and broadcaster Will Self, perhaps in a bid to ingratiate himself with audience members at Southport Arts Centre last night.

But probably not. After all, the po-faced journalist is hardly known for his charm.

But, whether or not it would please him to hear it, charming he was.

The award-winning writer took to the stage to give a reading from his latest book, *Liver*, as part of the Sefton Celebrates Writing Festival.

Self, best known for his satirical, grotesque and fantastic novels, chatted to the audience about the inspiration behind his latest literary offering, a collection of four stories, all relating in some way to the human liver.

Dressed in jeans and a black shirt, Self read extracts from each of the four tales, which ranged from the trials and tribulations of a modern-day Prometheus (this one works for a top London advertising agency) to a story told from the point of view of the Hepatitis C virus.

Perhaps most intriguing was his story about a liver cancer sufferer’s journey to Zurich, in order to be allowed to carry out her assisted suicide, which Self explained had been inspired by the story of Diane Pretty, a lady with motor neurone disease who fought to change the British law so she would be able to take her own life.

After a short interval, Self returned to dish out his sandwiches, and answer questions from his audience.

He listened with interest as readers commented on his books, and asked him about everything from walking, mental health and Dorian Gray to his thoughts on the possibility of life after death.

As he delivered witty, engaging and thoughtful responses, followers of his literary and television career settled back in their seats, delighted to be spending the evening in the company of such a gifted and fascinating man.

Injection missteps case ends in settlement deal

<http://www.lvrj.com>

By PAUL HARASIM

REVIEW-JOURNAL

Doctor doesn't admit he engaged in dangerous practice

Valley doctor must complete a course on sterile technique as part of settlement

A Las Vegas physician accused of injection practices similar to ones that triggered the nation's largest hepatitis C alert must complete a course on sterile technique and provide a medical board with a list of all patients he treated at the Gastrointestinal Diagnostic Clinic on Maryland Parkway.

But in the settlement agreement approved unanimously Thursday by the Nevada State Board of Osteopathic Medicine, Dr. Scott Young, who was fired by the clinic in March, stopped short of admitting he engaged in the dangerous practice of reusing syringes and vials of single-dose anesthetics on multiple patients.

As part of the settlement order by the board, Young agreed to: "Admit that the syringe practices as described by the complainants ... would constitute unprofessional conduct ... and if such practices were committed ... he (Young) accepts responsibility for his actions."

Brian Labus, the senior epidemiologist for the Southern Nevada Health District, has repeatedly said vials of single-dose medicine and syringes should never be reused because they can transfer tainted blood.

Young also was ordered to keep the board informed of any changes in his medical privileges or status at any of his practice locations.

The doctor, who has continued to work throughout the valley since he was fired in March from the clinic at 3196 S. Maryland Parkway, was unavailable for comment Thursday.

Similar behavior to what inspectors alleged Young engaged in was seen by authorities inspecting Dr. Dipak Desai's Endoscopy Center of Southern Nevada, resulting in 40,000 clinic patients being notified in February that they should be tested for a infectious diseases.

Nine cases of hepatitis C have been linked to Desai's clinics, and lawyers say hundreds of their clients have also contracted the disease there.

Board members did not discuss the settlement publicly before their vote at the Thursday evening meeting, which Young did not attend. There was no opportunity for questions.

Dr. Daniel Curtis, the chairman of the board, recused himself from voting on the settlement because he said he was a former business associate of Young. Board member Scott Manthei recused himself because he said he had been working recently with Young.

A state health inspectors' report of a Feb. 14 surprise visit at the Maryland Parkway clinic said surveyors observed Young using a syringe multiple times on the same vial of anesthetic and then using that vial multiple times on other patients.

Dorothy Sims, the registered nurse and health surveyor who signed the state report, told the Review-Journal in July that she stood by the report.

But in the seven-page settlement agreement that makes no mention of Sims, two other unnamed surveyors told board investigators that they did not witness reuse of the syringe.

"I wasn't positioned and I got interrupted where I could not see the whole process," one surveyor told the board.

According to the state report, Young told inspectors in an interview that it was not a problem to use an anesthetic on multiple patients.

"The anesthesiologist was asked what the process was when he went from a used Propofol (anesthesia) vial to a new patient," the report states. "The anesthesiologist states that he would change the needle and reuse the same syringe."

In a separate interview less than an hour later, Young then told inspectors he would discard the needle and syringe after each use, but not the vial of medicine.

But when questioned by a board investigator, Young denied that he ever told surveyors what they alleged he said.

"Young also claims that the complainants were simply confused about his conversations with them about the procedures," the settlement agreement reads.

Young also told board investigators that he would not use the same needle, syringe and vial on different patients because "he knows the vial, needle and syringe would be contaminated."

Marla McDade Williams, chief of the Bureau of Licensure and Certification, said Thursday that the clinic where Young once worked has had its license pulled by her agency, she said she could not say whether his behavior was responsible for that action.

The clinic had several other problems, according to state inspectors, including a lack of evidence that the center had "implemented a program for identifying and preventing infections."

Inspectors also found that a registered nurse was not in attendance with recovering patients.

Novel Therapy For Bleeding Gastric Varices

<http://www.medicalnewstoday.com>

Two patients with the diagnosis of liver cirrhosis and portal hypertension related to hepatitis infection were admitted to Shanghai Ruijin hospital due to recurrent melena and hematemesis. Isolated gastric varices were observed in the gastric fundus during the retroflexion of gastroscop. The authors carried out endoscopic sclerotherapy using cyanoacrylate combined with aethoxysklerol for bleeding gastric varices, which disappeared dramatically within six months after two sclerotherapies for each patient. The compound effect of obliteration by α -cyanoacrylate alkyl and eradication by aethoxysklerol was satisfying. No complication and clinical signs of gastrointestinal re-bleeding were observed during six months of endoscopic follow-up. Meanwhile, follow-up of these two patients are still under way.

A report article published on 14 June 2008, in the *World Journal of Gastroenterology* addresses this case. The research team led by Yun-Lin Wu and his colleagues in the Ruijin Hospital Affiliated to Shanghai Jiaotong University carried out endoscopic sclerotherapy successfully

using cyanoacrylate combined with aethoxysklerol for bleeding gastric varices, which disappeared dramatically within several months after two sclerotherapies for each patient.

CT portal angiography (CTPA) has come into wider spread of use in the assessment of variceal treatment and in further attempts to improve the results of endoscopic injection therapy. The authors detected the varices and made assessments of portosystemic collaterals through CTPA before sclerotherapy. After the injection of adhesives combined with sclerosants, CTPA revealed the vessels blocked by adhesive polymer, the obliteration and elimination of gastric varices, which were believed as a convincing sign of effective treatment.

Although the optimal treatment for gastric fundal variceal bleeding still remains controversial, the novel sclerotherapy using alpha -cyanoacrylate alkyl combined with aethoxysklerol could be an alternative and feasible method for obliteration and eradication of gastric fundal varices.

Article adapted by Medical News Today from original press release.

Reference:

Shi B, Wu W, Zhu H, Wu YL. Successful endoscopic sclerotherapy using cyanoacrylate combined with aethoxysklerol for bleeding gastric varices. World J Gastroenterol 2008;14(22): 3598-3601 <http://www.wjgnet.com/1007-9327/14/3598.asp>

InterMune Previews a Coming Attraction

<http://www.fool.com>

By Brian Lawler

After a relatively quiet few months for drug developer InterMune (Nasdaq: ITMN), on Wednesday the Rule Breakers pick announced more early clinical-trial results for its potential hepatitis C drug.

In advance of a major liver-disease conference in November, InterMune and development partner Roche released data and abstracts for protease inhibitor ITMN-191 from several preclinical and phase 1 studies of the drug.

Unlike some of ITMN-191's potential rivals, testing's still in too early a stage to draw definitive conclusions about its efficacy against competitors. That said, its initial results seem roughly comparable to other drugs' preliminary performance. In one 14-day study of patients who'd failed other hepatitis C therapies, ITMN-191 lowered the levels of hepatitis C in patients to roughly the same average level that Vertex's (Nasdaq: VRTX) telaprevir did in one of its first phase 1 studies among a similar patient group.

In Wednesday's release, InterMune also included some preclinical data testing ITMN-191 with other Roche hepatitis C compounds. Ironically, ITMN-191's future might depend as much on the success of one of Roche's hepatitis C partners as on its own.

Over the past several months, Vertex and Schering-Plough (NYSE: SGP) have been amassing mountains of positive clinical-trial data for their own antiviral protease inhibitors, telaprevir and boceprevir, both of which could compete with ITMN-191. InterMune and Roche have an ace up

their sleeve, though; they've been testing ITMN-191 in combination with other antiviral polymerase inhibitors from Roche and another Roche partner, Pharmasset (Nasdaq: VRUS).

If Roche's polymerase/protease inhibitor combinations work notably better (and no less safely) than Schering and Vertex's single-therapy approaches, ITMN-191 could become the protease inhibitor of choice for treating hep C. That will be particularly true if doctors display a preference for drugs proven in combination testing, rather than leaning toward Vertex or Schering's compounds.

Many potential hep C compounds that produced solid preclinical data, like ViroPharma (Nasdaq: VPHM) and Wyeth's (NYSE: WYE) HCV-796, have later been felled by safety issues, so the verdict is still out on ITMN-191's longer-term chances. Whatever the compound's fate, InterMune's immediate future will be shaped more by the phase 3 study results due next January for its pulmonary fibrosis drug pirfenidone. If successful, InterMune could have pirfenidone approved for marketing and on sale in early 2010. In that case, more positive early-stage results for ITMN-191 could be icing on the cake for InterMune investors.

'Hepatitis B shot doesn't raise multiple sclerosis risk'

<http://www.newkerala.com>

Washington, Sep 26 : Most of the children immunised against hepatitis B are not at an increased risk of developing multiple sclerosis (MS), but those who received a certain type of the vaccine are, according to a new study.

The France based study involved 349 children with MS and 2,941 healthy children, all under 16. A total of 24.4 percent of them with MS were vaccinated for hepatitis B in the three years before the study, compared to 27.3 percent for the children without MS.

Although the study found that hepatitis B vaccination does not generally increase the risk of multiple sclerosis, the children with MS were 1.74 times more likely to have received a certain type of hepatitis B vaccine, called Engerix B.

Those children with MS developed symptoms three or more years after the vaccine. The risk was only found for this specific type of hepatitis B vaccine and not found for all vaccines against hepatitis B.

This association cannot be taken as confirmation that the vaccine caused MS. Further studies are needed to determine whether this is a causal relationship, according to a statement by the American Academy of Neurology. The findings will be published in the October online issue of *Neurology*, the journal of the academy.

--- IANS