



*California Pacific
Medical Center*

A Sutter Health Affiliate

MEDIA RELEASE

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**First Ever Test of Gene Silencing Therapy for Hepatitis B
*Patient Doing Well After Undergoing Innovative RNAi Treatment***

(San Francisco, January 11, 2008) California Pacific Medical Center in San Francisco has become the first medical research institution in the world to use a gene silencing therapy to treat Hepatitis B.

California Pacific teamed up with Pennsylvania-based Nucleonics Inc. (<http://www.nucleonicsinc.com>), and other investigators worldwide, to test an innovative method of helping people suffering from the Hepatitis B virus (HBV), which is the second leading cause of cancer worldwide.

“This is an exciting time, and a potentially important new way of helping people battle what can be a deadly disease,” says Robert Gish, M.D., medical director of the Liver Disease Management & Transplant Program at California Pacific Medical Center. “We need a more advanced therapy to hopefully shorten the duration of our current therapies, that are used indefinitely in most patients with chronic hepatitis B.”

Currently most people who have chronic HBV infections undergo life-long therapy to keep the virus at bay. If left unchecked, HBV can cause cirrhosis or scarring of the liver, liver cancer, liver failure, and even death in 1 out of 4 people infected with the virus.

When HBV infects a liver cell it creates strands of genetic material called RNA and then uses the RNA to turn the cell into a mini HBV factory, effectively churning out new copies of the virus which spread throughout the liver.

In this new RNAi approach, the patient gets an infusion of plasmids, or circular segments of DNA. Once in the liver these segments then produce something called “short interfering RNA” (siRNA) which then bind to the HBV RNA. The siRNA then uses a molecular scissor effect to destroy the viral RNA, essentially blocking the virus’ ability to replicate itself in the liver cell. By preventing HBV from multiplying, this method effectively paralyzes the virus and makes it unable to create infectious virus particles.

“We hope that by immobilizing the virus we can give the patient’s body a chance to fight back against it, and perhaps even clear HBV from their body completely,” says Stewart Cooper, M.D., director of California Pacific’s Liver Immunology Laboratory. “If this treatment is effective, it could potentially help patients get off long-term treatment indefinitely.”

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According to the Centers for Disease Control and Prevention, an estimated 2 million Americans are chronically infected with HBV. There is no cure and the medications currently available to treat it can also induce some undesirable side effects. Because there are usually no symptoms, the virus is often not discovered until it has already done considerable damage to the liver.

This is the first phase of clinical studies to test the safety and efficacy of the treatment. This round involves giving patients a brief, five-minute infusion of the genetic material to assess its safety.

All patients enrolled in the trial undergo a thorough consenting process involving two physicians. The first explains the trial, its goals and potential, as well as its possible risks. The physician then leaves the room and a second physician reviews the information with the patient again to make sure that he/she fully understands everything that is involved.

This approach has been approved by the FDA, the CPMC Institutional Review Board, the institutional bio-safety committee, a special CPMC research committee and the National Institutes of Health.

California Pacific Medical Center. Beyond Medicine.

At San Francisco's California Pacific Medical Center, we believe in the power of medicine. We research the most up-to-date treatments, hire and work with the most qualified individuals, and practice the most modern, innovative medicine available. We deliver the highest quality expert care, with kindness and compassion, in acute, post-acute and outpatient services, as well as preventive and complementary medicine. But we also believe that medicine alone is only part of the solution. That's why we look intently at each individual case and treat the whole person, not just the illness. It's why we go beyond medical care and provide our patients with things like disease counseling, family support and wellness treatments. As one of California's largest private, community-based, not-for-profit, teaching medical centers, and a Sutter Health affiliate, we are able to reach deep into our community provide education, screening and financial support in some of the city's most underserved neighborhoods. Because medicine can transform a body. But going beyond medicine can transform a life. <http://www.cpmc.org>

About Nucleonics, Inc.

Nucleonics, founded in January 2001, is an emerging biotechnology company focused on the development of novel RNA interference-based therapeutics for viral and other diseases. Privately owned, Nucleonics is headquartered in Horsham, Pennsylvania. For more detailed information about how the Nucleonics RNAi approach to treatment works, please visit <http://www.nucleonicsinc.com/tech/index.html>

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