

UC San Diego Medical Center Offers Gene Therapy Clinical Trial for Advanced Heart Failure

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UC San Diego Medical Center is currently enrolling patients in a Phase 2 clinical trial of an investigational drug for the treatment of advanced heart failure. The “Calcium Up-Regulation by Percutaneous Administration of Gene Therapy in Cardiac Disease,” or CUPID, study is evaluating a new gene-based therapy designed to stimulate production of an enzyme that enables the heart to pump more effectively.

Initial data from the first phase of the CUPID trial, reported on November 9th at the American Heart Association Scientific Sessions 2008, demonstrated that the drug had an acceptable safety profile in the first group of patients. This study will be the second phase of the trial.

“The CUPID trial is designed to rescue a failing heart by replacing an enzyme known to play a critical role in healthy cardiac function,” said Barry Greenberg, M.D., director of the Advanced Heart Failure Program at UC San Diego Medical Center and president of the Heart Failure Society of America. “The objective of the study is not only to improve the symptoms of heart failure, but importantly, to reverse the severity of the disease in patients.”

The Phase 2 trial compares the use of a drug called MYDICAR at two or three dose levels with placebo, an inert substance. CUPID is expected to enroll 46 patients with advanced heart failure at 13 U.S. medical centers. The clinical trial drug is delivered in a single dose directly to the heart muscle during a short outpatient procedure performed in a cardiac catheterization laboratory. CUPID is funded by Celladon Corporation, makers of MYDICAR.

Heart failure is the leading medical cause of hospitalization and is expected to result in estimated direct and indirect costs to the healthcare system in 2008 of \$35 billion. Despite important therapeutic advances in drug and device therapies, the prognosis of heart failure patients remains poor.

About 5 million people in the United States have heart failure, and another 550,000 new cases are diagnosed each year. Heart failure contributes to or causes about 280,000 deaths annually. The most common symptoms of heart failure are shortness of breath, feeling tired, and swelling in the ankles, feet, legs, and sometimes the abdomen. There is no cure for heart failure.

The Advanced Heart Failure Program at UC San Diego Medical Center is dedicated to providing the most beneficial, state-of-the-art, yet cost-effective medical care for patients with advanced heart failure. As part of the Sulpizio Family Cardiovascular Center, patients have access to the newest investigational drugs and devices, cardiac resynchronization therapy, implantable defibrillators, ablation therapy for atrial and ventricular arrhythmias, left ventricular assist devices, and the most advanced cardiac surgical techniques.

Patients interested in enrolling in this clinical trial at UC San Diego Medical Center may call 619-543-7723.

About UC San Diego Health Sciences

UC San Diego Health Sciences encompasses the School of Medicine, the Skaggs School of Pharmacy and Pharmaceutical Sciences, and UCSD Medical Center – the system of patient services provided at UCSD Medical Center-Hillcrest; UCSD Thornton Hospital-La Jolla; Shiley Eye Center, and the Moores UCSD Cancer Center, one of 41 centers in the United States to hold a National Cancer Institute (NCI) designation as a Comprehensive Cancer Center. As a top-ranked academic medical institution, the role of UC San Diego Health Sciences is to consistently provide both local and global leadership in improving health through innovative research, education and patient care.

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