CEDARS-SINAI MEDICAL CENTER. NEWS

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EXPERIMENTAL HEARTPOD™ SYSTEM IMPLANTED IN FIRST L.A. PATIENT, BEING EVALUATED IN PATIENTS WITH CONGESTIVE HEART FAILURE

WHAT: Cardiologists at Cedars-Sinai Medical Center have implanted a patient with congestive heart failure with the first experimental HeartPod™ system in the greater Los Angeles area. Cedars-Sinai is one of only three sites in the United States participating in a prospective, multi-center, non-randomized, open label research study of this system. The system is also being evaluated at sites in New Zealand and Australia.

The experimental HeartPod™ System was developed by researchers at Cedars-Sinai and is being tested to evaluate its potential to provide patients with congestive heart failure with an alternative to repeated heart catheterization in order to obtain data regarding pressure build-up in the heart.

WHY: The goal of this study, which will involve about 25 patients over a five-year period, is ultimately to see if using this type of implanted sensor to guide therapy can prevent episodes of worsening heart failure and thus improve symptoms and reduce the need for repeat hospitalization. An estimated 5 million Americans suffer from congestive heart failure, and approximately 400,000 new cases are diagnosed each year.

WHO: P. K. Shah, M.D., director, Division of Cardiology, Cedars-Sinai Medical Center, is principal investigator of this study, and is available for interviews.

HOW: According to Dr. Shah, patients with congestive heart failure often experience shortness of breath and pressure in their chest due to a build-up of fluids in their lungs due to an increase in the pressure of blood inside the left side of the heart. Previously, the only way to measure this pressure was for the patient to undergo multiple heart catheterizations in a cath lab.

The experimental HeartPod™ System, however, implants a tiny, permanent sensor in the heart wall. This is done under local anesthetic in a heart catheterization lab. The sensor is positioned on the tip of a catheter and inserted into a major vein. The catheter is then threaded through the vein to the heart's upper chambers where the sensor is implanted in the left side of the wall separating the upper right and upper left chambers of the heart. The sensor is then connected to an antenna, which is implanted in the patient's abdomen under the skin. The experimental device is designed to send physiologic data – including pressure, EKG, and temperature

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information – to an external portable hand-held pocket PC-type of device by wireless frequency communication. Thus, the patient and his or her physicians can take readings and evaluate the amount of pressure build-up at any point in time, without need for repeated cardiac catheter insertion.

(Cedars-Sinai owns the patent on the device described above and has licensed this product to Savacor, Inc., a division of St. Jude Medical, the sponsor of the research. Dr. Neal Eigler, a staff cardiologist at Cedars-Sinai and inventor of the device, is the CEO and a major shareholder of Savacor, Inc. Some of the other physicians participating in this study also have a financial relationship with Savacor, Inc. The Principal and Sub-Investigator of the study do not have any financial interest in this study.)

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