

CardioMEMS Completes CHAMPION Clinical Trial Study

Study results indicate that the CardioMEMS implantable hemodynamic monitoring system significantly reduces the leading cause of hospitalizations in the U.S.

Atlanta – June 1, 2010. The CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outomes in NYHA Class III Patients) trial met its primary efficacy endpoint with a 30% reduction in heart failure hospitalization rates at 6 months ($p < 0.001$) in heart failure patients whose treatment was guided by pulmonary artery pressures obtained through a miniature, permanent wireless implant.

The results were presented this week at the European Society of Cardiology Heart Failure Congress 2010 in Berlin, Germany, by the principal investigators of the trial: William Abraham, M.D., Director of the Division of Cardiovascular Medicine at The Ohio State University Medical Center, and Philip Adamson, M.D., Director of the Heart Failure Institute at the Oklahoma Heart Hospital. The study was sponsored by CardioMEMS, Inc., a medical technology company that has developed a novel wireless sensing and communication technology for the human body.

The CHAMPION trial evaluated the safety and effectiveness of CardioMEMS' heart failure (HF) pressure measurement system in New York Heart Association Class III (NYHA Class III) heart failure patients; these patients experience symptoms of heart failure with only mild exertion. NYHA Class III represents roughly 1.5 million of the six million heart failure patients in the U.S., and historically accounts for nearly half of all heart failure hospitalizations.

The CHAMPION Trial enrolled 550 patients, who had been hospitalized for heart failure in the previous year, at 64 leading heart centers in the U.S. All subjects received the heart failure sensor as a permanent pulmonary artery implant and were then randomized to the treatment or control group before discharge. Prior to enrollment in the CHAMPION study, these patients were being treated by heart failure specialists at leading centers and were receiving optimal drug, device and disease management therapy.

The reduction in the risk of a heart failure related hospitalization at 6 months was 30% and the impact on hospitalizations continued to increase over time, reaching 38% per year over the full duration of the trial. The average patient follow-up was 15 months. The safety profile of the device was positive: none of the implanted sensors needed to be removed or replaced and all were functioning throughout the course of the trial.

"Pulmonary artery pressure monitoring using the CardioMEMS Champion™ Heart Failure Pressure Management System represents our first meaningful improvement for the management of heart failure in nearly a decade," said Dr. Abraham. "We were pleased to see that the patient benefit was robust and durable and actually increased beyond the primary endpoint of 6 months; this is a key point for patients, doctors and the healthcare system."

Dr. Adamson added, "The CHAMPION trial illustrates how monitoring of patients with chronic heart failure can reduce the need for costly hospitalizations while improving quality of life. These trial results hold great promise for patients suffering from chronic symptomatic heart failure."

The wireless heart failure sensor is an innovative miniature device that is implanted into the patient's pulmonary artery using a simple, catheter-based technique. Following the procedure, patients perform wireless measurements of their pulmonary artery pressure from home. The pressure data is immediately transmitted to a secure database and is available for review by the patient's physician or nurse on the CardioMEMS Champion website.

"Frequent and unpredictable hospitalizations are very traumatic for heart failure patients and their families and we are gratified to be able to reduce their occurrence," said Jay Yadav, M.D., Co-Founder and CEO of CardioMEMS and cardiologist at the Piedmont Heart Institute. "Using the Champion Heart Failure Management System, doctors can obtain critical information that previously required a cardiac catheterization. Patients can perform these readings from their homes and with this vital information, doctors and nurses can more effectively take care of their patients and keep them out of the hospital."

Caution – Investigational Device. Limited by federal law to investigational use.

About CardioMEMS, Inc.

CardioMEMS is a medical device company that has developed and is commercializing proprietary wireless sensing and communication technology for the human body. Its technology platform is designed to improve the management of severe chronic cardiovascular diseases such as aneurysms, heart failure and hypertension. CardioMEMS miniature wireless sensors can be implanted using minimally-invasive techniques and transmit cardiac output, blood pressure and heart rate data which are critical to the management of patients. The sensors can be permanently implanted into the heart and blood vessels due to their small size, durability and lack of wires and batteries. Using radiofrequency (RF) energy, the sensors transmit real-time data to external electronic readers, which then communicate this information to the patient's physician. More information about CardioMEMS is located at www.cardiomems.com.

Statements made in this press release that look forward in time or that express beliefs, expectations or hopes regarding future occurrences or anticipated outcomes are forward-looking statements. A number of risks and uncertainties such as risks associated with product development and commercialization efforts, expected timing or results of any clinical trials, ultimate clinical outcome and perceived or actual advantages of the Company's products, market and physician acceptance of the products, intellectual property protection, and competitive offerings could cause actual events to adversely differ from the expectations indicated in these forward looking statements.

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