BioControl Launches International, Multi-Center, Clinical Study of the CardioFit™ System for Heart Failure in Europe, Israel and Australia

Early data show that the CardioFit system is safe to implant in patients with NYHA class III heart failure

Yehud, Israel, January 10, 2007 --- BioControl Medical (http://www.biocontrol-medical.com/), developer of advanced implantable devices for the treatment of autonomic disorders, announced today that it is enrolling patients for an international, multi-center, open-label clinical study of the CardioFit system for the treatment of Congestive Heart Failure at IRB approved sites in Europe, Israel and Australia.

CardioFit is a new electrical stimulator system designed to improve heart function through the controlled stimulation of the vagus nerve. Pre-clinical and preliminary clinical data demonstrate that vagus nerve stimulation has a therapeutic role in treating heart failure as it may reduce the heart rate and ventricular volumes in addition to restoring regular rhythm. The CardioFit system has also been found to provide the same benefit when used simultaneously with other existing optimal medical therapies.

"The CardioFit system is a novel therapy designed for a clinically unmet need. Of the existing neurostimulation device therapies currently in clinical development for cardiology indications, the CardioFit system is clearly the most advanced and has the most significant probability for success," said BioControl CEO Dr. Ehud Cohen.

It is estimated that approximately 1.2% to 2% of the global population and as many as 10% of individuals 65 years and older suffer from heart failure, a serious condition defined by the inability of the heart to provide adequate output to the body. Causes of heart failure include hypertension, ischemic heart disease and valvular disease.

"I have recruited several patients to the study thus far. It is my opinion that the CardioFit system has great potential as a useful treatment for heart failure," said Professor Peter Schwartz, the study's principal investigator at Policlinico S.Matteo University Hospital in Pavia, Italy.

The primary endpoint of the study is to determine the occurrence of all adverse events resulting from the system and/or the implant procedure. Secondary endpoints include symptomatic, functional, and structural status as well as a review of biological serum markers. Study investigators will collectively enroll 20 to 30 patients, between the ages of 18 and 75, who meet the inclusion/exclusion criteria. Patients enrolled in the study will be followed by the study investigators for a period of one year.

"I have closely followed the development of the CardioFit™ system and am hopeful that sites in the U.S. will soon join the clinical program and begin enrolling for this very important study," said Dr. Paul Hauptman, Director of Heart Failure, Saint Louis University Hospital, St. Louis, Missouri.

The trial has been approved by Institutional Review Boards at the following prestigious clinical sites in Europe, Israel and Australia.

- Policlinico S.Matteo University Hospital in Pavia, Italy: Prof. Peter J. Schwartz.
- Otto-von-Guericke University Hospital, Magdeburg, Germany: Prof. Helmut Klein.
- University Hospital Maastricht, Maastricht, Netherlands: Prof. Harry Crijns.
- Ospedali Riuniti , Bergamo, Italy: Dr. Antonello Gavazzi.
- Clinical Center of Serbia, Belgrad, Serbia:, Dr. Goran Milasinovic.
- Royal Melbourne Hospital, Melbourne, Australia: Prof. Harry Mond.
- Chaim Sheba Medical Center, Tel Hashomer, Israel: Prof. Micha Eldar.

BioControl develops and markets advanced implantable devices for the treatment of autonomic disorders, conditions whereby the autonomic nervous system ceases to function properly, resulting in a disruption to the control of involuntary body processes. The devices enable controlled electrical stimulation of various nerves to achieve therapeutic results. In April 2006, American Medical Systems exclusively licensed BioControl's technology for its miniaturo™ system, to develop it as a treatment device for urge incontinence and interstitial cystitis. Funds secured from that transaction are being used to support the development of the CardioFit system for the treatment of Congestive Heart Failure.

For more information on how to enroll in the CardioFit study, please contact: info@biocontrol-medical.com. To schedule an interview with BioControl CEO Dr. Ehud Cohen, please contact Marjie Hadad, media liaison, at +972-54-536-5220 or send an e-mail to marjie@biocontrol-medical.com.