Pilot Study Extension Indicates Long-Term Treatment Durability with BioControl Medical's CardioFit® System

The Associated Press

YEHUD, Israel & NEW HOPE, Minn.--(BUSINESS WIRE)--Nov 8, 2012--BioControl Medical has announced that pilot study extension results unveiled at the American Heart Association Scientific Sessions 2012 have indicated durability of treatment with its CardioFit® system for heart failure. Presented on November 7 in "Long-term Benefits of Vagal Nerve Stimulation Therapy in Heart Failure," the extended study data showed that the CardioFit's favorable clinical effects - as demonstrated by improved hemodynamics, quality of life and six-minute walk test - were maintained in patients beyond the study's original six- and 12-month evaluation points, up to 24 months. 1 "These results are an encouraging validation of vagus nerve stimulation's potential as an effective long-term treatment for heart failure," said Dr. Srdjan Raspopovic, Clinical Center of Serbia, Belgrade, Serbia, a CardioFit pilot study investigator who presented the data at AHA 2012. "Larger controlled studies are currently underway to confirm these findings, and if they do, we believe that VNS will become an important new treatment alternative in the heart failure armamentarium." Conducted in Italy, Germany, The Netherlands and Serbia, the original multi-center pilot clinical study of the CardioFit was designed to assess the six-month safety and clinical response to the therapy in 32 patients with NYHA II-IV heart failure on optimized background medical therapy. Study data showed that patients experienced sustained significant improvement across key clinical measures at six and 12 months, including left ventricular function and structure, heart rate variability, and resting heart rate. 2 Patients also showed improvement in self-reported quality of life surveys and six-minute hall walk tests. 2 The study extension's 24-month data, available on 19 patients, showed sustained clinical improvement with the CardioFit therapy. Patient follow up now extends beyond four years, with good therapy tolerance and no reported safety issues.

"The extended pilot results are important data that build on BioControl Medical's growing body of research supporting VNS for the treatment of heart failure," said Ehud Cohen, Ph.D., chief executive officer of BioControl Medical. "We thank the investigators for their rigorous work assessing the long-term effects of CardioFit in our early study, and we look forward to gathering more data on a broader population of patients as our pivotal clinical trial continues to advance." The safety and efficacy of the CardioFit is being explored further in the INOVATE-HF (INcrease Of VAgal TonE in Heart Failure) global, multi-center, investigational device exemption (IDE) clinical study. Initiated in April 2011, INOVATE-HF is a prospective, randomized, controlled clinical study that will evaluate the system's potential to reduce hospitalization and death among patients with HF, while also exploring whether combined treatment with CardioFit and prescription drug therapy is more effective than drug therapy alone. 3 INOVATE-HF will ultimately enroll up to 650 patients at up to 80 centers in the United States and Europe. Results of the

INOVATE-HF study will be used to support a Premarket Approval Application (PMA) to the U.S. Food and Drug Administration (FDA) for market clearance of CardioFit.

About the CardioFit The CardioFit system consists of a stimulator, a sensor lead and a stimulation lead, which are implanted under the skin of the chest. The sensor lead is extended from the stimulator to the right ventricle of the heart, and the stimulation lead is extended from the stimulator to the vagus nerve on the right side of the neck. Once activated, the stimulator's electrical pulses are transferred via the stimulation lead to the vagus nerve. At the same time, the sensor lead monitors changes in heart activity and turns stimulation on or off accordingly. Like a pacemaker, the CardioFit System can be programmed on and off via external wireless communication with the device.

About BioControl Medical Headquartered in Yehud, Israel with offices in New Hope, Minn., BioControl Medical 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. For more information on BioControl Medical, visit www.biocontrol-medical.com [1].

Caution: In the United States, the CardioFit is an investigational device. Limited by Federal (or United States) law to investigational use.

References 1 Dennert R, et al. "Long-term Benefits of Vagal Nerve Stimulation Therapy in Heart Failure." American Heart Association Scientific Sessions 2012.

2 De Ferrari GM, Crijns HJ, Borggrefe M, Milasinovic G, Smid J, Zabel M, Gavazzi A, Sanzo A, Dennert R, Kuschyk J, Raspopovic S, Klein H, Swedberg K, Schwartz PJ. "Chronic vagus nerve stimulation: a new and promising therapeutic approach for chronic heart failure." Eur Heart J (2011) 32 (7): 847-855.

3 Hauptman PJ, Schwartz PJ, Gold MR, Borggrefe M, Van Veldhuisen DJ, Starling, RC, Mann DL. "Rationale and study design of the INcrease Of Vagal TonE in Heart Failure study: INOVATE-HF." American Heart Journal (June 2012) 163 (6): 955-962.

CONTACT: Nobles Communications Laura Nobles, 310-795-0497 laura@noblescommunications.com [2] KEYWORD: UNITED STATES NORTH AMERICA MINNESOTA MIDDLE EAST ISRAEL INDUSTRY KEYWORD: HEALTH CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES RESEARCH FDA SCIENCE SOURCE: BioControl Medical Copyright Business Wire 2012 PUB: 11/08/2012 07:00 AM/DISC: 11/08/2012 07:00 AM http://www.businesswire.com/news/home/20121108005574/ [3]

Source URL (retrieved on *06/20/2013 - 12:01am*):
http://www.mdtmag.com/news/2012/11/pilot-study-extension-indicates-long-term-treatment-durability-biocontrol-medical%E2%80%99s-cardiofit%C2%AE-system?qt-

recent_content=0

Links:
[1] http://www.biocontrol-medical.com
[2] mailto:laura@noblescommunications.com
[3] http://www.businesswire.com/news/home/20121108005574/