# BioControl Medical’s VNS Technology Shown Effective for Treating Epilepsy; Early Clinical Experience Presented at AES 2012

The Associated Press

YEHUD, Israel--(BUSINESS WIRE)--Dec 3, 2012--BioControl Medical has announced that the FitNeS™ implantable vagus nerve stimulation system for treating epilepsy, which employs the same platform technology used in the company’s CardioFit ® system for treating congestive heart failure, has been shown effective in initial cases performed at Sahlgrenska University Hospital, Gothenburg, Sweden. Data on five patient cases, which were presented by Prof. Bertil Rydenhag, Prof. Hans Silander, and Prof. Elinor Ben-Menachem at the American Epilepsy Society 2012 meeting in San Diego on December 1, have demonstrated improved clinical outcomes and an absence of side effects in patients who received treatment with the device. 1 The FitNeS(TM) implantable vagus nerve stimulation system, with core technology from BioControl Medical (Yehud, Israel). (Photo: Business Wire) FitNeS, which was launched commercially in Europe by BioControl Medical spin-off company CerebralRx, is designed to treat epilepsy patients with partial onset seizures who do not achieve full seizure control with available prescription drugs (or those with “refractory epilepsy”). In the five reported cases, the device was successfully implanted in patients whose condition was refractory to multiple anti-epileptic drugs, including two patients who had received resective epilepsy surgery and three others who were inoperable for this epilepsy procedure.

All patients were followed for a minimum of one year post-implantation with FitNeS, with the longest follow-up duration of 15 months. As of the AES abstract presentation date, seizure frequency reduction versus baseline was 25 percent in one patient and more than 50 percent in the other four patients, at current strengths between 1.5 and 1.75 mA. 1 In addition, no device- or procedure-related side effects were reported by patients, relatives, friends or the treating physician. 1 “The early results of treatment with FitNeS are very encouraging. Even at relatively high currents, we are seeing positive outcomes in efficacy and an absence of side effects experienced by patients,” said Prof. Ben-Menachem, the physician monitoring these patients. “If larger studies are able to confirm these initial findings, I believe that FitNeS has the potential to become a preferred treatment option for patients with refractory epilepsy.” FitNeS consists of an implanted stimulator and stimulation lead, which work together to deliver electrical signals to the left vagus nerve. Designed to deliver targeted, unidirectional nerve stimulation, the system effectively activates nerve fibers toward the brain while minimizing the activation of non-related nerve fibers and surrounding tissues. This selective approach has the potential to increase stimulation effectiveness while minimizing risk of side effects.

The FitNeS system was developed to offer a new treatment option for refractory epilepsy patients while delivering improvements over existing vagus nerve

stimulation devices. In addition to its potential to increase stimulation efficacy and minimize side effects, the FitNeS system was designed to employ lower currents, minimize nerve damage through a unique nerve electrode interface, reduce current leakage through improved cuff isolation, and allow for safe and easy explant of the electrode if required.

"These early results with FitNeS are another great validation of BioControl Medical's proprietary neuromodulation technology, which has been shown to offer a number of unique benefits over first generation platforms," said Ehud Cohen, Ph.D., chief executive officer. "We see tremendous global opportunity for our technology in treating both heart disease and neurological disorders, and we look forward to a strong future of growth in both areas." The FitNeS system has CE marking and is available in Europe through CerebralRx, which holds exclusive rights to BioControl Medical's platform vagus nerve stimulation technology for treating neurological disorders. FitNeS is not available in the United States.

About CerebralRx Based in Yehud, Israel, CerebralRx was founded in 2010 as a spin-off of BioControl Medical to develop breakthrough implantable neuromodulation systems for the treatment of autonomic nervous system-related neurological disorders. The company's flagship product is the FitNeS system, an implantable vagus nerve stimulation device for treating patients with refractory epilepsy. CerebralRx plans to expand the applications of BioControl Medical's technology for treating additional disorders, including Alzheimer's and treatment resistant depression.

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 Rydenhag B, Silander H, Ben-Menachem E. "Preliminary Experience with a New System for Vagus Nerve Stimulation." American Epilepsy Society 2012
Photos/Multimedia Gallery
Available:http://www.businesswire.com/multimedia/home/20121203005516/en/
CONTACT: Nobles Communications Laura Nobles, (310) 795-0497 laura@noblescommunications.com KEYWORD: MIDDLE EAST ISRAEL INDUSTRY KEYWORD: HEALTH MEDICAL DEVICES GENERAL HEALTH SOURCE: BioControl Medical Copyright Business Wire 2012 PUB: 12/03/2012 07:00 AM/DISC: 12/03/2012 07:00 AM http://www.businesswire.com/news/home/20121203005516/

**Source URL (retrieved on *10/26/2014 - 1:15am*):**
http://www.mdtmag.com/news/2012/12/biocontrol-medical%E2%80%99s-vns-technology-shown-effective-treating-epilepsy-early-clinical-experience-presented-aes-2012?qt-recent_content=0&qt-video_of_the_day=0