



August 15, 2016

EnteroMedics Announces Publication of 24 Month ReCharge Clinical Study Data in Obesity Surgery

- vBloc® Therapy Demonstrates Durable Weight Loss, Reduction of Comorbidities, and Favorable Safety Profile at 24 Months -

ST. PAUL, Minn., Aug. 15, 2016 /PRNewswire/ -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced the publication of 24 month results from the Company's ReCharge Clinical Study. The article, titled "Two-Year Outcomes of Vagal Nerve Blocking (vBloc) for the Treatment of Obesity in the ReCharge Trial," was published in *Obesity Surgery* (DOI: 10.1007/s11695-016-2325-7), and is available online [here](#).



"The ability to sustain meaningful weight loss is vital when considering a viable long term solution for treating obesity and its related comorbidities," said Caroline M. Apovian, MD, FACP, FACN, Director, Nutrition and Weight Management, Professor of Medicine at Boston University School of Medicine, and lead author of the article. "vBloc has consistently set itself apart, demonstrating sustained weight loss combined with a compelling safety profile. These findings underscore vBloc Therapy's potential to serve as a favorable, effective therapy in patients struggling with obesity who prefer not to undergo an anatomy-altering or lifestyle-restricting bariatric procedure."

Durable Weight Loss

The ReCharge Pivotal Trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial of vBloc Neurometabolic Therapy in 239 patients with obesity. At 24 months, 76% percent of the randomized vBloc participants (n=123) remained in the trial. The mean excess weight loss (EWL) among vBloc participants who presented for their 24-month visit was 21%, with a mean percent total weight loss (TWL) of 8%. Of the 24 Sham control patients who had not yet crossed over to vBloc at 24 months, the EWL and TWL was 4% and 1%, respectively. The authors noted that comparative randomized controlled trials for conventional bariatric procedures demonstrated only 6% TWL for laparoscopic adjustable gastric banding (LAGB) at the same time point. Patients' quality of life improvements, as measured by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, were shown to be durable with a sustained increase of 20 units from their preoperative level, and the Three-Factor Eating Questionnaire (TFEQ) showed that patients continued to have a 50% reduction in hunger.

Comorbidity Improvements

Among participants with pre-diabetes or metabolic syndrome at baseline, approximately 50% demonstrated resolution of pre-diabetes or metabolic syndrome at 24 months compared to baseline. Among the subset of participants with abnormal cardiovascular or metabolic conditions at baseline, statistically significant improvements were observed in mean low density lipoprotein (LDL) cholesterol (-16 mg/dL) and high density lipoprotein (HDL) cholesterol (+4 mg/dL), triglycerides (-46 mg/dL), systolic (-11 mmHg) and diastolic blood pressures (-10 mmHg), and hemoglobin A1c (HbA1c) (-0.3 %).

Safety Benefits

The authors noted that the safety profile of vBloc Therapy remained favorable at 24 months compared to complications observed with conventional bariatric procedures such as sleeve gastrectomy and gastric bypass. Ninety-four percent of all adverse events were reported as mild or moderate in severity, and 83% of events had resolved by 24 months. Three

serious adverse events were reported and adjudicated by the independent clinical events committee to be unrelated to vBloc therapy.

"Without altering the anatomy of the gastrointestinal system, vBloc's potential for serious adverse events is minimal, and the ReCharge study helps solidify this important fact. vBloc's safety profile may serve as a future benchmark for obesity treatment options," said Scott A. Shikora, MD, FACS, Chief Medical Officer of EnteroMedics.

"These findings are crucial as we continue to advance towards our goals of both expanding the reach of this proven technology, as well as obtaining reimbursement for patients in need," says Dan Gladney, Chief Executive Officer of EnteroMedics. "These results, in combination with the first-hand patient success stories we've had the privilege of learning about, leave us confident that vBloc combined with the vBloc Achieve program, a comprehensive, personalized weight loss support program to help vBloc patients reach and maintain health goals, hold strong potential to serve as a highly effective option in patients in dire need of new approaches to treat their obesity."

About EnteroMedics Inc.

EnteroMedics is a medical device company focused on the development and commercialization of its neuroscience based technology to treat obesity and metabolic diseases. vBloc[®] Neurometabolic Therapy, delivered by a pacemaker-like device called the Maestro[®] Rechargeable System, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. EnteroMedics' Maestro Rechargeable System has received U.S. Food and Drug Administration approval and CE Mark approval.

Information about the Maestro[®] Rechargeable System and vBloc[®] Neurometabolic Therapy

You should not have an implanted Maestro Rechargeable System if you have cirrhosis of the liver, high blood pressure in the veins of the liver, enlarged veins in your esophagus or a significant hiatal hernia of the stomach; if you need magnetic resonance imaging (MRI); if you have a permanently implanted, electrical medical device; or if you need a diathermy procedure using heat. The most common related adverse events that were experienced during clinical study of the Maestro Rechargeable System included pain, heartburn, nausea, difficulty swallowing, belching, wound redness or irritation, and constipation.

Talk with your doctor about the full risks and benefits of vBloc Therapy and the Maestro Rechargeable System. For additional prescribing information, please visit www.enteromedics.com.

If you are interested in learning more about vBloc Neurometabolic Therapy, please visit www.vbloc.com or call 1-800-MY-VBLOC.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements about EnteroMedics Inc. Our actual results could differ materially from those discussed due to known and unknown risks, uncertainties and other factors including our limited history of operations; our losses since inception and for the foreseeable future; our limited commercial sales experience with our Maestro[®] Rechargeable System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; our ability to regain and then maintain compliance with the Nasdaq continued listing requirements; our ability to commercialize our Maestro System; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for any modifications to our Maestro System; physician adoption of our Maestro System and vBloc[®] Neurometabolic Therapy; our ability to obtain third party coding, coverage or payment levels; ongoing regulatory compliance; our dependence on third party manufacturers and suppliers; the successful development of our sales and marketing capabilities; our ability to raise additional capital when needed; international commercialization and operation; our ability to attract and retain management and other personnel and to manage our growth effectively; potential product liability claims; potential healthcare fraud and abuse claims; healthcare legislative reform; and our ability to obtain and maintain intellectual property protection for our technology and products. These and additional risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange Commission, particularly those factors identified as "risk factors" in the annual report on Form 10-K filed March 28, 2016. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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