



November 4, 2015

## **vBloc® Therapy Data Demonstrate Two Year Maintenance of Clinically Significant Weight Loss and Sustained Improvements in Obesity Related Risk Factors**

### **EnteroMedics Announces Chief Medical Officer, Scott A. Shikora, M.D., F.A.C.S., Awarded 2015 Outstanding Achievement Award from ASMBS Results and Award Presented at Obesity Week, November 2-6, 2015**

ST. PAUL, Minn., Nov. 4, 2015 /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 presentation of two year follow up results from the ReCharge Study of vBloc Neurometabolic Therapy in obesity. The results were presented in two abstracts at Obesity Week 2015, a joint Annual Meeting of the American Society of Metabolic and Bariatric Surgery and The Obesity Society taking place in Los Angeles November 2-6, 2015.

"Among the major challenges with obesity treatment are maintaining weight loss over time and avoiding the health risks associated with weight gain and cycling," said Scott Shikora M.D. F.A.C.S, EnteroMedics Executive Vice President and Chief Medical Officer. "At the two-year follow-up, data from the ReCharge Trial demonstrate that intermittent vagal blocking provides maintenance of clinically significant weight loss and a continued favorable safety profile. These data also demonstrate meaningful and sustained reduction in measures of cardiovascular risk factors, improvements in indicators of pre-diabetes and metabolic syndrome, as well as improvements in weight-related quality of life and eating behaviors, pointing to vBloc as a safe and effective long-term weight loss solution."

The Company also announced that Dr. Shikora was awarded the 2015 Outstanding Achievement Award from the American Society of Metabolic and Bariatric Surgery (ASMBS). The ASMBS Foundation's Outstanding Achievement Award honors an ASMBS member who supports the goals and vision of the ASMBS Foundation, has displayed a lasting impression and selfless commitment to the ASMBS organization and has made significant contributions to the field of metabolic and bariatric surgery.

### **Weight Loss at 24 Months**

The ReCharge pivotal trial is a prospective double-blind, sham-controlled clinical trial of vBloc Neurometabolic Therapy for the treatment of obesity. The trial includes 239 randomized (2:1) patients with a BMI of 40-45kg/m<sup>2</sup> or 35-40 kg/m<sup>2</sup> with at least one obesity-related condition(s). The double-blind period of the ReCharge Trial has been completed and the trial has transitioned to a 5-year, open-label study of the safety and effectiveness of vagal blocking.

Percent excess weight loss (EWL), percent total body weight loss (TBL) and safety in subjects randomized to the active arm of the trial who attended the two-year visit (n=103) were presented. Seventy-six percent of subjects remained in the active arm of the trial. Sham subjects were in the process of crossing over to an active device at the 2-year visit.

At 2 years, the average weight loss was 21% ± 25% EWL or 8% ± 10% TBL. Fifty-eight percent of subjects had at least 5% TBL and 45% had at least 7.5% TBL. Only one serious complication has occurred in the 2 years.

### **Obesity Related Condition Results in vBloc Group at 24 Months**

In addition to EWL, metabolic parameter improvements were sustained to 24 months:

<b>Risk Factor</b>	<b>Time Point</b>	<b>All Subjects</b>	<b>Subjects with Abnormal Baseline Values</b>
<b>Systolic BP (mmHg)</b>	Screening	128 ± 13	142 ± 10
	24 month change	-6***	-11***
<b>Diastolic BP (mmHg)</b>	Screening	81 ± 9	89 ± 8
	24 month change	-3**	-10***
<b>Waist Circumference (cm)</b>	Screening	121 ± 12	123 ± 11
	24 month change	-8***	-10***
<b>LDL Cholesterol (mg/dL)</b>	Screening	122 ± 32	151 ± 21

	24 month change	-5**	-16***
<b>Triglycerides (mg/dl)</b>	Screening	139 ± 61	209 ± 42
	24 month change	-14*	-46***
<b>HbA1c (%)</b>	Screening	5.7 ± 0.6	5.9 ± 0.2
	24 month change	-0.3***	-0.3***

\*P < 0.05. \*\* P < 0.01. \*\*\* P < 0.001

Lastly, for those patients with either pre-diabetes or metabolic syndrome at baseline, the 2 year data showed 50% remission rate for pre-diabetes and 47% remission rate for metabolic syndrome.

### About the ReCharge Study

The ReCharge Pivotal Trial of vBloc Neurometabolic Therapy for the treatment of obesity is a prospective double-blind, sham-controlled clinical trial involving 239 randomized (2:1) patients with a Body Mass Index (BMI) of 40-45kg/m<sup>2</sup> or 35-40 kg/m<sup>2</sup> with at least one obesity-related condition(s). The trial tested the effectiveness and safety of vBloc Therapy utilizing EnteroMedics' Maestro® Rechargeable (RC) System. All patients participated in a weight management counseling program.

### 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, CE Mark and is listed on the Australian Register of Therapeutic Goods.

### 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](http://www.enteromedics.com).

If you are interested in learning more about vBloc Therapy, please visit [www.vbloc.com](http://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 lack of 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 comply 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 13, 2015. 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.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/vbloc-therapy-data-demonstrate-two-year-maintenance-of-clinically-significant-weight-loss-and-sustained-improvements-in-obesity-related-risk-factors->

[300172386.html](#)

SOURCE EnteroMedics Inc.

News Provided by Acquire Media