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vBloc® Neurometabolic Therapy Demonstrates 34% Excess Weight Loss in ReCharge Study Patients with Moderate Obesity and a Comorbidity

Data Presented at the International Federation for the Surgery of Obesity and Metabolic Diseases 20th World Congress in Vienna, Austria

ST. PAUL, Minn., Sept. 1, 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 that analyses of the ReCharge Study demonstrated Excess Weight Loss (EWL) of 34% and significant improvements in obesity-related risk factors for vBloc® Therapy treated, moderately obese patients who had at least one comorbidity. These data were presented at the International Federation for the Surgery of Obesity and Metabolic Diseases 20th World Congress in Vienna, Austria on August 26, 2015.

"These subgroup analyses of the ReCharge Study, which demonstrated excess weight loss of 34% and major improvements in obesity related risk factors, show the profound and clinically meaningful effect of vBloc Therapy in patients with a Body Mass Index (BMI) of 35-40 kg/m²," said Scott Shikora M.D. F.A.C.S, EnteroMedics Executive Vice President and Chief Medical Officer, "These results show significant benefits as it relates to weight loss and relief of comorbidities and improved safety relative to anatomy altering and restrictive procedures, making vBloc an attractive alternative for those patients unwilling to undergo more drastic procedures to regain their health."

Weight Loss and Safety Results at 12 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/m² or 35-40 kg/m² with at least one obesity-related condition(s). These analyses of the ReCharge Study evaluated the efficacy, safety and comorbidity impact of vBloc Therapy (n=53) and sham (n=31) on patients with moderate obesity (BMI 35-40 kg/m²) and one or more comorbidities.

Mean EWL at 12 months in the per-protocol group (defined as subjects with 12 month data, correct treatment randomization who received treatment within 45 days of implant) was 34±26% (95% CI, 26 to 41) in vBloc group and 19±18% (95% CI, 12 to 27) in sham group. 87% of the subjects remained in both groups at the end of the 12 months. No serious device-related complications were observed in the first year.

Obesity Related Condition Results in vBloc Group at 12 Months

Parameter	Baseline	12Month	Change	95%CI
SBP(mmHg)	130±11	124±13	-5.6±13	[-9.5, -1.6]
DBP(mmHg)	80±9	78±8	-2.7±9	[-5.4, 0.1]
Fasting Glucose(mg/dL)	101±20	93±14	-7.3±15	[-12.1, -2.5]
HR(bpm)	76±10	70±8	-6.4±10	[-9.3, -3.6]
Total Cholesterol(mg/dL)	216±36	202±37	-13.2±34	[-23.6, -2.9]
HDL(mg/dL)	55±16	55±13	0.2±9	[-2.6, 3.0]
LDL(mg/dL)	131±35	123±34	-6.6±33	[-16.7, 3.4]
TG(mg/dL)	150±62	117±53	-34.0±57	[-51.3, -16.6]
Mean±S.D.				

Subject Demographics

	vBloc Treatment Group	Sham Control Group
# of Subjects	53	31
BMI (kg/m ²)	38±2	38±2
Age (Years)	53±8	51±7
Female/Male	42/11	25/6

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/m² or 35-40 kg/m² 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.

If you are interested in learning more about vBloc 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 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-neurometabolic-therapy-demonstrates-34-excess-weight-loss-in-recharge-study-patients-with-moderate-obesity-and-a-comorbidity-300136233.html>

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