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Journal of the American Medical Association Publishes EnteroMedics' ReCharge Pivotal Trial Results

ST. PAUL, Minn., Sept. 3, 2014 /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 results from the Company's ReCharge Pivotal Trial of VBLOC Vagal Blocking Therapy delivered via the Maestro® System for the treatment of patients with obesity in the September 3, 2014 issue (doi:10.1001/jama.2014.10540) of *The Journal of the American Medical Association (JAMA)*.

"Obesity is a complex and widely under-treated metabolic disease with serious consequent morbidities, including cancer, diabetes and cardiovascular disease," said Charles Billington, MD, one of the national Co-principal Investigators of the ReCharge Trial, who is Professor of Medicine and Director of Medical Weight Management at the University of Minnesota and Minneapolis VA Medical Center, and the senior author of the publication. "Existing options are insufficient, and have created a gap between medications and bariatric surgery that a device like the Maestro System might bridge."

The ReCharge Pivotal Trial of VBLOC® Vagal Blocking Therapy for the treatment of obesity is a prospective double-blind, sham-controlled clinical trial involving 239 randomized patients (233 implanted) enrolled at ten sites in the United States and Australia. The trial tested the effectiveness and safety of VBLOC Therapy utilizing EnteroMedics' Maestro® Rechargeable (RC) System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to VBLOC treatment or sham control groups.

As previously reported, VBLOC Therapy-treated patients in the ReCharge Study intention to treat (ITT) group, which included all 239 patients randomized, demonstrated a clinically meaningful excess weight loss (EWL) of 24.4% at 12 months that was statistically significant as compared to the rigorous sham control group. These VBLOC patients also maintained their weight loss with 25% EWL at 18 months and 21% EWL at 24 months. At 12 months, the majority (52.5%) lost 20% or more of their excess weight and nearly one-third of VBLOC Therapy treated patients lost 30% or more. Statistically significant improvements were observed in the VBLOC Therapy treatment group in total cholesterol, LDL, triglycerides, systolic and diastolic blood pressure, heart rate and waist circumference. The implant/revision procedure, device or therapy-related serious adverse event rate among VBLOC Therapy treated patients was 3.7% for the treatment arm, well below the prespecified threshold of 15%.

The U.S. Food and Drug Administration (FDA) is currently reviewing EnteroMedics' Premarket Approval (PMA) application for approval of the Maestro Rechargeable System as a treatment for obesity. In June, the FDA Gastroenterology and Urology Devices Panel (GUDP) voted 6 to 2 "in favor," with 1 abstention, that the benefits of the Maestro System outweigh its risks. EnteroMedics anticipates an FDA approval decision in 2014. The Maestro® System received CE Mark certification in 2009 and was listed on the Australian Register of Therapeutic Goods in 2011.

Obesity Facts and Figures

According to the Centers for Disease Control and Prevention (CDC), more than one-third of U.S. adults live with obesity. The estimated annual cost of obesity in the U.S. was \$147 billion in 2008, accounting for more than twice previous estimates, approximately 21 percent, of U.S. healthcare costs.^{1,2} The World Health Organization estimates that higher BMI is a major risk factor for comorbidities such as cardiovascular disease, the leading cause of death in 2012, diabetes, hypertension, musculoskeletal disorders and some cancers. By 2030, another 65 million people will be considered obese, placing half of all men and between 45-52% of all women in this category. This could also mean an additional 7.8 million cases of diabetes and 6.8 million cases of heart disease.³

About VBLOC® Therapy and the Maestro® System

EnteroMedics developed VBLOC® vagal blocking therapy to offer bariatric surgeons and their patients a less invasive alternative to existing surgical weight loss procedures that may present significant risks and alter digestive system anatomy, lifestyle and food choices. VBLOC Therapy is delivered via the Maestro® System through laparoscopically implanted leads to intermittently block the vagus nerves using high-frequency, low-energy electrical impulses. VBLOC Therapy is designed to target the multiple digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

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® vagal blocking 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, which helps control both hunger and fullness. VBLOC allows people with obesity to take a positive path towards weight loss, addressing the lifelong challenge of obesity and its comorbidities without sacrificing wellbeing or comfort. EnteroMedics' Maestro Rechargeable System has received CE Mark and is listed on the Australian Register of Therapeutic Goods.

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 regulatory approval for our Maestro® System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; our preliminary findings from our EMPOWER™ and ReCharge pivotal trials; 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® vagal blocking 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 27, 2014. 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.

Caution - Investigational device. Limited by Federal (United States) law to investigational use.

The implantation procedure and usage of the Maestro® System carry some risks, such as the risks generally associated with laparoscopic procedures and those related to treatment as described in the ReCharge clinical study informed consent.

¹ Eric A. Finkelstein, Justin G. Trogon, Joel W. Cohen and William Dietz Annual Medical Spending Attributable To Obesity: Payer-And Service-Specific Estimates *Health Affairs*, 28, no.5 (2009):w822-w831 (published online July 27, 2009; 10.1377/hlthaff.28.5.w822)

² Cawley, John, and Chad Meyerhoefer. "The Medical Care Costs of Obesity: An Instrumental Variables Approach." *Journal of Health Economics* 31.1 (2012): 219-30.

³ Wang, Y., et. al. "Health and economic burden of the projected obesity trends in the USA and the UK" *The Lancet*, [Volume 378, Issue 9793](#), Pages 815 - 825, 27 August 2011.

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