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EnteroMedics Announces Three Year Diabetes, Hypertension and Weight Loss Data from the Maestro® RC System DM2 ENABLE Study

DM2 ENABLE Study data to be presented today at the 19th Annual Meeting of the International Federation for the Surgery of Obesity and Metabolic Disorders

ST. PAUL, Minn., Aug. 28, 2014 /PRNewswire/ -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, announced that three year diabetes, hypertension and weight loss data from the Company's DM2 ENABLE Study of VBLOC® vagal blocking therapy delivered via the Maestro® Rechargeable (RC) System will be presented today at the 19th Meeting of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) being held August 26-30, 2014 in Montreal, Canada. The presentation will be delivered by Scott Shikora, MD, FACS, Associate Professor of Surgery, Harvard Medical School, Director, Center for Metabolic and Bariatric Surgery, Brigham and Women's Hospital and EnteroMedics' Consulting Chief Medical Officer.

"Results from the DM2 ENABLE study of reversible vagal nerve blocking with the implantable Maestro Rechargeable System continue to demonstrate both medically meaningful weight loss as well as improvement in diabetes control in obese subjects with Type II Diabetes Mellitus. Most significantly, the benefits of VBLOC Therapy are sustained through the 36 month follow-up period of the trial with continued excellent overall and cardiovascular safety profiles," said Dr. Shikora. "These data continue to support the widely accepted role of bariatric surgery in the treatment of metabolic disorders."

VBLOC-DM2 ENABLE Study Data

The DM2 Study is an international, open-label, prospective, multi-center study designed to evaluate the safety and efficacy of VBLOC® vagal blocking therapy delivered via the Maestro® RC System in 28 diabetic subjects with obesity by measuring average percentage excess weight loss (EWL), HbA1c (blood sugar), fasting plasma glucose (FPG, blood sugar) and blood pressure, following device activation. To date, no deaths or unanticipated adverse device effects have been reported during the VBLOC-DM2 ENABLE Study and the safety profile is similar to that seen in other VBLOC clinical trials.

At 36 months, HbA1c levels dropped from 7.6% at baseline to 7.0% ($p=0.04$), which according to the American Diabetes Association, is the reasonable target for many adults with diabetes and has been shown to reduce microvascular complications of diabetes. Furthermore, 83% of the patients who were being treated with one or more diabetic medications at the start of the trial reported no change, a decrease or discontinuation of their medication suggesting that the progression of their diabetes had been modified.

In combination with the HbA1c results, three year fasting plasma glucose (from 155.6 mg/dl at baseline to 131.5 mg/dl ($p=0.015$)) and excess weight loss of 24.3% ($p < 0.0001$) continue to demonstrate the long-term stability of VBLOC Therapy as both a weight loss and a promising metabolic disease intervention. Of note, the improvement in blood pressure at 36 months (mean arterial pressure -7.3 mm/Hg ($p=0.14$)) in hypertensive patients was also maintained. These metabolic effects in diabetes, hypertension and weight loss are consistent with previous findings from other time points and are considered medically meaningful improvements.

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.

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