February 12, 2014

EnteroMedics Announces Food and Drug Administration Advisory Committee Meeting Date for Review of the Maestro(R) Rechargeable System for the Treatment of Obesity

Center for Devices and Radiologic Health Advisory Committee Scheduled for May 29, 2014

ST. PAUL, MN -- (Marketwired) -- 02/12/14 -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that the U.S. Food and Drug Administration's Office of Device Evaluation has scheduled a meeting of the Center for Devices and Radiologic Health's (CDRH) Advisory Committee on Thursday, May 29, 2014 to review the Maestro® System delivering VBLOC® vagal blocking therapy as a treatment for morbid obesity. The CDRH Advisory Committee is an independent panel of clinical and scientific experts that helps evaluate medical devices for safety and efficacy and makes recommendations regarding Benefit-Risk to the FDA.

EnteroMedics' PMA application for VBLOC Therapy, which was accepted for review by the FDA in July of 2013, contains data from the Company's ReCharge Pivotal Study. The ReCharge Pivotal Study is a randomized, double-blind, sham-controlled, multicenter pivotal clinical study in 239 randomized patients (233 implanted) at 10 sites testing the effectiveness and safety of VBLOC Therapy utilizing EnteroMedics' second generation Maestro System.

"We are pleased that the FDA has decided to move the PMA application for our innovative technology forward towards possible approval by scheduling an Advisory panel meeting to discuss the Maestro System. We very much look forward to presenting VBLOC Therapy to the panel members as we work to address the significant and widening gap in treatment alternatives for obesity and its associated diseases," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "We will continue to focus on thoroughly preparing for panel with the goal of delivering on the promise of this new treatment option to the millions of Americans who suffer with 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. EnteroMedics' proprietary technology, 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. 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.

About the ReCharge Pivotal Study

The ReCharge Pivotal Study is a randomized, double-blind, sham-controlled, multicenter pivotal clinical study in 239 randomized patients (233 implanted) at 10 sites testing the effectiveness and safety of VBLOC® vagal blocking therapy utilizing EnteroMedics' second generation Maestro® Rechargeable (RC) System. All patients in the study received an implanted device and were randomized in a 2:1 allocation to treatment or control groups. The control group received a non-functional device during the study period. In February 2013, EnteroMedics announced that its ReCharge Study demonstrated a statistically significant and clinically meaningful excess weight loss (EWL) outcome and excellent safety profile. This included an average EWL of approximately 25% for VBLOC Therapy-treated patients, with over 50% of those patients achieving at least a 20% EWL. While the results demonstrated an excellent safety profile that met the pre-specified study measures, with both a positive benefit-risk equation and a medically meaningful and clinically significant effect over the control group, the results did not meet the study's predefined super-superiority efficacy endpoints.

About VBLOC® Therapy

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 Maestro® System

The Maestro® System delivers VBLOC® vagal blocking therapy via two small electrodes that are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach.

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 studies; 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 studies; 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 7, 2013. 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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Source: EnteroMedics