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EnteroMedics Announces PMA Application for VBLOC Therapy in Obesity Accepted for Review and Filing by FDA

ST. PAUL, MN -- (Marketwired) -- 07/25/13 -- 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 (FDA) has accepted for filing the Company's Premarket Approval (PMA) application for approval of the Maestro® Rechargeable System's VBLOC® vagal blocking therapy as a treatment for obesity.

"The Maestro System holds the potential to fill a significant gap in the obesity treatment landscape, offering a unique, patient-friendly approach to addressing the long term challenges associated with obesity," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "FDA acceptance for filing of our PMA application is an important step toward this goal. We look forward to working closely with the FDA during the review process, continuing through an advisory committee panel and approval decision, as we prepare for U.S. commercialization of the Maestro System."

As previously announced, the FDA indicated in a pre-PMA meeting that, subject to a detailed review of the submitted data, the Company can anticipate presenting the PMA before a future FDA Advisory Committee panel. The accepted PMA application includes data from the Company's ReCharge Pivotal Trial, a prospective, double-blind, sham-controlled clinical trial involving 239 randomized patients (233 implanted) at ten sites in the United States and Australia.

About Maestro Rechargeable (RC) System

The Maestro® RC 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. The Maestro RC System is powered by an internal, rechargeable battery. The battery is recharged via an external mobile charger and transmit coil that the patient uses for a short time each week. The Maestro RC System has received CE Mark and has been listed on the Australian Register of Therapeutic Goods.

About the ReCharge Pivotal Trial

The ReCharge Pivotal Trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial 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 trial 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 trial period. In February, EnteroMedics announced that its ReCharge Trial 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 trial 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 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.

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 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 trial informed consent.

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