



## **EnteroMedics Announces Completion of Patient Enrollment and Device Implantation in the ReCharge Pivotal Trial for Obesity**

### **Announces Approval of Six of the Eight Remaining Class III Components by the Therapeutic Goods Administration**

ST. PAUL, MN -- (MARKET WIRE) -- 12/28/11 -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that it has completed enrollment and device implantation in the Company's ReCharge pivotal trial for obesity. A total of 233 patients have been successfully implanted at 10 clinical sites in the U.S. and Australia. The ReCharge trial is a randomized, double-blind, parallel-group, multicenter pivotal study testing the effectiveness and safety of VBLOC® vagal blocking therapy, delivered via EnteroMedics' Maestro® Rechargeable (RC) System, in the treatment of obesity. VBLOC Therapy is a first-in-class weight loss treatment which is designed to control both hunger and fullness by regulating the primary nerve which controls the digestive system. It is designed to be minimally invasive and to address the lifelong challenge of obesity by empowering the individual to take positive steps along a path toward weight loss without compromising their anatomy or lifestyle.

The Company also announced that in addition to receiving the previously announced initial approvals for the critical active implantable medical device (AIMD) components of the Maestro System by the Therapeutic Goods Administration (TGA) for the listing on the Australian Register of Therapeutic Goods (ARTG), EnteroMedics has also received approval for six of the eight remaining individual class III components.

Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer, commented: "Full enrollment and implantation of the ReCharge trial is an important milestone for EnteroMedics. With this, we begin the 12 month blinding period of the trial in continuation of our plans for U.S. registration. This milestone achievement, combined with approval for ARTG listing by the TGA of most of the components of the Maestro System and European CE mark certification, significantly advanced our global commercialization efforts for this patient-friendly therapy in 2011."

For additional information on the ReCharge study, please visit [www.RechargeStudy.com](http://www.RechargeStudy.com).

#### *About the ReCharge Pivotal Trial*

The ReCharge Pivotal Trial is a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 233 patients 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. All patients are expected to participate in a weight management counseling program.

#### *About the 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 received CE Mark in March 2011.

#### *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 electrical impulses. VBLOC Therapy is designed to target the multiple metabolic and digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

#### *About EnteroMedics Inc.*

EnteroMedics is a development stage medical device company focused on the design and development of devices that use

neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. EnteroMedics' proprietary neuroblocking technology, VBLOC® vagal blocking therapy, is designed to intermittently block the vagus nerves using high-frequency electrical impulses. These electrical impulses are delivered by a neuroregulator, EnteroMedics' Maestro® System, which is powered by an integrated rechargeable battery. For more information, visit [www.enteromedics.com](http://www.enteromedics.com).

*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 the European Community; our preliminary findings from our EMPOWER™ pivotal trial; 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 current report on Form 8-K filed September 28, 2011. 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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