



EnteroMedics Receives First Approval for the Active Implantable Medical Device Components of the Maestro System From Australian Therapeutic Goods Administration (TGA)

Review of Remaining Components Continues

ST. PAUL, MN -- (MARKET WIRE) -- 12/13/11 -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic disease and other gastrointestinal disorders, today announced approval by the Australian Therapeutic Goods Administration (TGA) of the critical active implantable medical device (AIMD) components of the Maestro® System, a first-in-class, safe, effective and sustainable weight loss treatment which is designed to control both hunger and fullness by blocking the primary nerve which regulates the digestive system.

TGA approval was granted for the Maestro Implant Kit, which is comprised of a rechargeable neuroregulator, anterior and posterior leads and a clinician transmit coil, as well as the individual implantable rechargeable neuroregulator component, both of which were AIMD applications. In addition, TGA approved the two class I applications for the AC battery charger and the programmer cable. The TGA continues review of the balance of the individual class III components, which include the mobile charger, multiple versions of the patient transmit coil and the clinician programmer.

"The implantable AIMD components of the Maestro System are the heart of our system and of EnteroMedics' revolutionary approach to obesity treatment. Their approval by the TGA, therefore, marks a major milestone for EnteroMedics and a significant accomplishment for both our company and our many collaborators in the Australian healthcare community," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "The Maestro System is the only surgical intervention to individually address each patient's path toward weight loss without compromises in safety, lifestyle or anatomy. We look forward to completion of the review of the balance of the system components and to the opportunity to provide the Australian bariatric care community with a new, safe and sustainable option for addressing the epidemic of obesity in this important market."

About Obesity in Australia

According to the Australian Bureau of Statistics, in 2008 sixty-two percent of all adults in Australia were either overweight (BMI > 25) or obese (BMI > 30). It is estimated that by 2025, 7.2 million Australians could be obese. The Australian Federal Minister has declared obesity a national priority, with obesity related costs exceeding \$21 billion annually. Approximately 13,900 bariatric surgeries were performed in Australia in 2008.

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, 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 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, low-energy, 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.

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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Source: EnteroMedics

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