



## **EnteroMedics Achieves Major Milestones in Global Regulatory and Commercialization Strategy for the Maestro System**

### **Company Receives Conditional Approval of Investigational Device Exemption; Announces Plans to Commercialize the Maestro RC System in Australia**

ST. PAUL, MN, Aug 02, 2010 (MARKETWIRE via COMTEX News Network) -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced that the Company has received conditional approval for its Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA). The IDE outlines plans for conducting a pivotal trial, the ReCharge Trial, evaluating the safety and efficacy of VBLOC(R) vagal blocking therapy delivered via the Company's second-generation Maestro(R) RC System in the treatment of obesity. The Maestro System is the first obesity treatment to use neuroblocking technology and represents a less invasive alternative to existing surgical weight loss procedures, which alter digestive system anatomy, lifestyle and food choices and may present significant risks.

The Company also announced its plans to commercialize the Maestro RC System in Australia and expects to file an application for approval and listing with the Australian Therapeutic Goods Administration (TGA) upon receiving CE Mark certification for the Maestro RC System. EnteroMedics hopes to receive TGA approval during the second half of 2011. The Company continues to explore commercialization opportunities in other markets outside of the United States.

With the decision to commercialize in Australia, the Company recently entered into formal discussions with the Australian Institute of Weight Control (AIWC), a network of surgical clinics specializing in laparoscopic weight loss surgery and clinical research for the morbidly obese, to become the first group of surgeons to implant the Maestro RC System commercially when Australian regulatory approval is obtained. The discussions also include the intent to enter into an agreement between AIWC and EnteroMedics under which AIWC will provide services including surgeon and clinic training as well as research, regulatory affairs, marketing, and reimbursement support related to the Maestro RC System in Australia.

"EnteroMedics has achieved two key objectives in its effort to bring a safe and effective treatment option to major global markets where obesity has become an epidemic," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "Conditional approval of our IDE application is the next step forward toward U.S. regulatory approval for VBLOC Therapy. Importantly, the ReCharge trial also advances our second-generation Maestro RC System. Insight gained from the over 400 patients worldwide treated with VBLOC Therapy provides us with the confidence to embark on our commercialization path outside the U.S. and look ahead to the ReCharge study as part of our U.S. commercialization strategy."

Commenting on EnteroMedics' discussions with the AIWC, Dr. Knudson said: "The AIWC group of surgeons are internationally known, have extensive experience with the Maestro System, have participated with EnteroMedics in our earliest clinical studies and are strong advocates for this new therapy. The AIWC is an ideal partner for the commercialization of the Maestro System in Australia, a country whose rate of obesity surgery has risen over 800 percent in the last decade."

James Toouli, M.D., professor of surgery at Flinders University in Adelaide, Australia, and a member of the AIWC Board, commented: "The surgical treatment of obesity, one of the only consistently effective means of delivering clinically meaningful weight loss, requires that the patient make compromises in anatomy, safety, diet and lifestyle, which frequently turns them away from treatment. Controlling obesity is a critical goal for modern society, as its costs present an ever increasing strain on our healthcare systems. AIWC believes that the Maestro System may provide obese patients with the first option to achieve clinically meaningful weight loss without the compromises of current treatment options."

#### About the ReCharge Pivotal Trial

EnteroMedics' IDE application outlines plans for conducting a prospective, randomized, multicenter controlled trial in 234 morbidly obese subjects designed to evaluate the safety and efficacy of the Maestro RC System in treating obesity. All subjects in the study would receive an implanted device and would be randomized to treatment or control groups. All subjects will be expected to participate in a weight management program. The primary efficacy objective is designed to observe a 20% EWL difference between the treated and the control groups (a statistical superior superiority margin test of 10% will be used). There is a secondary efficacy objective similarly related to EWL difference between groups determined by the Met Life method at 12 months. A co-primary efficacy responder analysis of the number of treated subjects who achieve at least 20% and 25% EWL at 12 months is also included. Both primary efficacy objectives are based on BMI method calculation and must be met for the trial to be successful. The primary safety objective is to demonstrate a 12 month Serious Adverse Event rate of less than 15%. The

Company plans to initiate the ReCharge trial process in the second half of 2011.

#### About the AIWC

The AIWC is a network of multi disciplinary weight loss surgical clinics specializing in laparoscopic weight loss surgery for the morbidly obese. It consists of three partner clinics in Perth, Adelaide and Sydney, with expansion plans for other centers in Australia. The AIWC works with public and private organisations to develop treatment platforms for the morbidly obese, striving for continual clinical improvement through leadership research and training programs. The AIWC performed more than 1,250 bariatric procedures in 2009 and have a base of over 7,000 patients. The bariatric surgeons of the AIWC were among the first in the world to implant the Maestro System and have participated in all of EnteroMedics' clinical studies to date.

#### 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 VBLOC Therapy

EnteroMedics developed VBLOC(R) 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(R) 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 and other gastrointestinal disorders. EnteroMedics' proprietary neuroblocking technology, VBLOC(R) 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 which is powered either by an external controller (Maestro RF System) or an integrated rechargeable battery (EnteroMedics' second-generation Maestro RC System). EnteroMedics is currently conducting a feasibility study examining VBLOC Therapy's effects on blood glucose levels in diabetic patients outside of the United States. 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 regulatory approval for our Maestro(R) System for the treatment of obesity; our preliminary findings from our EMPOWER(TM) 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(R) 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; 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; potential 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 Company's Form 10-K dated March 29, 2010. 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 U.S. Federal law to investigational use.

The implantation procedure and usage of the Maestro(R) System carry some risks, such as the risk generally associated with laparoscopic procedures and those related to treatment as described in the EMPOWER clinical trial informed consent.

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