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Treatment of Type 2 Diabetes Mellitus added to EnteroMedics CE Mark for Obesity

ST. PAUL, Minn., Sept. 29, 2014 /PRNewswire/ -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that its CE Mark for the Maestro® Rechargeable (RC) System for obesity was expanded to include the management of Type 2 diabetes mellitus through improved glycemic control.

"Diabetes and obesity are among the biggest public health challenges of the 21st century," said Ken Fujioka, Director of the Center for Weight Management, Scripps Clinic division of Diabetes and Endocrinology. "The relationship between these two diseases is well understood and the reason why novel treatment options like VBLOC Therapy, which targets multiple metabolic mechanisms, are needed to not only effectively treat obesity, but offer patients the opportunity to improve their glycemic control."

The Maestro System initially received CE Mark in 2009 for the treatment of obesity (Body Mass Index of 30 to 55) and is listed on the Australian Register of Therapeutic Goods. CE Mark is a conformance mark granted by the European Commission that provides marketing approval in the countries of the European Economic Area, and that is recognized by many nations, including Australia.

"The expansion of our CE Mark certification for the Maestro System recognizes the clinically meaningful, sustainable improvement in glycemic control observed in Type 2 diabetes patients with obesity receiving VBLOC Therapy," stated Mark B. Knudson, Ph.D., President and Chief Executive Officer of EnteroMedics. "This certification allows us to emphasize the clinical benefits of the Maestro System beyond just weight loss to include its effects on the serious co-morbidities of obesity, in key markets around the world."

The CE Mark for the diabetes indication was supported by data from the Company's multiple clinical trials, including the DM2 ENABLE Study of VBLOC® vagal blocking therapy delivered via the Maestro RC System in diabetic subjects with obesity.

VBLOC-DM2 ENABLE Study Data

The DM2 Study is an international, open-label, prospective, multi-center study designed to evaluate the safety and efficacy of VBLOC® vagal blocking therapy delivered via the Maestro® RC System in 28 diabetic subjects with obesity by measuring average percentage excess weight loss (EWL), HbA1c (blood sugar), fasting plasma glucose (FPG, blood sugar) and blood pressure, following device activation. To date, no deaths or unanticipated adverse device effects have been reported during the VBLOC-DM2 ENABLE Study and the safety profile is similar to that seen in other VBLOC clinical trials.

As reported at the 19th Annual Meeting of the International Federation for the Surgery of Obesity and Metabolic Disorders, the metabolic effects of VBLOC Therapy at three years in diabetes, hypertension and weight loss were consistent with previous findings from other time points and are considered medically meaningful improvements. The reductions at 36 months from baseline in HbA1c (from 7.6% to 7.0% (p=0.04)), fasting plasma glucose (from 155.6 mg/dl to 131.25 mg/dl (p=0.0145)) and excess weight loss of 24.3% ($p < .0001$) continue to show the long term sustainability of VBLOC Therapy as a weight loss and promising metabolic disease intervention. In addition, of the 18 patients who were being treated with one or more diabetic medications at the start of the trial, 83% had either completely stopped taking their medication, reduced the dose of medication, or had no increase in the amount of medication they were taking by 36 months.

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. 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, which helps control both hunger and fullness. 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 27, 2014. 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.

SOURCE EnteroMedics Inc.