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EnteroMedics Begins Post-Approval Study for the Treatment of Obesity with vBloc Therapy

Study Designed to Further Demonstrate Long-Term Safety and Efficacy of vBloc for Weight Loss in Obese Patients

ST. PAUL, Minn., Sept. 5, 2017 /PRNewswire/ -- EnteroMedics Inc. (NASDAQ:ETRM), a developer of minimally invasive medical devices to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced the start of its U.S. FDA post-approval study of the vBloc® System, a medical device used to treat obesity. The ReNEW Study: Maestro New Enrollment Post-Approval Study (ReNEW) will evaluate the long-term safety and effectiveness of the vBloc® System for weight loss in obese patients in a real-world clinical setting.

The first patient in the company's ReNEW Study was enrolled late last week at NYU Winthrop Hospital in Mineola, NY, by the site's principal investigator (PI), Dr. Collin Brathwaite, MD, FACS, FASMBS; Chairman of Surgery and Chief of the Division of Minimally Invasive Surgery, Director of the Bariatric Surgery Program.

"We are so pleased to both participate in the ReNEW Study, as well as to provide vBloc as a covered benefit for all of our employees at NYU Winthrop Hospital," said Dr. Brathwaite. "vBloc is an important innovation in the weight loss care continuum that provides patients with access to a minimally invasive, non-anatomy altering solution to obesity that has been shown in clinical trials to improve patient outcomes."

ReNEW is a five-year, multi-center trial that will provide 200 patients with vBloc® Neurometabolic Therapy at approximately 10-15 centers across the United States. All patients will participate in a weight management program consisting of recommendations regarding diet, exercise, and behavior modification throughout the study. The primary safety objective of ReNEW is to demonstrate that the rate of serious adverse events (SAEs) related to implanting vBloc is statistically lower than 25% at five years. Primary efficacy endpoints for ReNEW will examine various measures of excess weight loss (EWL) and total body weight loss (TBL).

There are currently three centers with IRB approval for the ReNEW Study. Separately, EnteroMedics is working in collaboration with Kaiser Permanente on a Type 2 Diabetes Study with vBloc and is concurrently running its vBloc Now program, which offers commercial patients access to vBloc Therapy at a reduced-cost with the goal of collecting additional real-world outcomes data to support reimbursement.

"With recent focus on real-world evidence by the FDA, post-approval studies such as ReNEW allow physicians to follow the safety and efficacy of new treatments in a more complex and diverse patient population than is typically studied in pre-approval clinical trials," said Dan Gladney, Chairman, President and Chief Executive Officer of EnteroMedics. "Our ability to work with our physician partners to begin this post-approval study is further evidence of EnteroMedics' commitment to help the obesity community gain additional insights about the clinical and economic benefits of vBloc."

The Maestro Rechargeable System was approved by the U.S. Food and Drug Administration on January 14, 2015.

For more information on EnteroMedics' ReNEW Study, please visit: https://clinicaltrials.gov/ct2/show/NCT03145636

About vBloc® Therapy

vBloc Therapy works to control sensations of hunger using a pacemaker-like device that is implanted under the skin during a safe, minimally invasive procedure that does not alter or remove any patient anatomy. The vBloc System is designed to give the patient a sensation of fullness, empowering them to eat less, control their appetite, and lose weight. Studies have shown that vBloc Therapy produces meaningful weight loss while also reducing comorbidity factors related to obesity.

vBloc Therapy is approved for use in people aged 18 years and older who are obese, with a BMI of 40 to 45 kg/m2, or a BMI of 35 to 39.9 kg/m2 with a related health condition such as Type 2 diabetes, high blood pressure, high cholesterol levels or obstructive sleep apnea who have had a poor response to trying to lose weight under supervision in the last 5 years.

About EnteroMedics Inc.

EnteroMedics is a medical device company focused on the development and commercialization of technology to treat obesity and metabolic diseases. vBloc® Neurometabolic Therapy, delivered by an FDA-approved pacemaker-like device called the vBloc® System, is designed to help patients feel full and eat less by intermittently blocking hunger signals on the vagus nerve. EnteroMedics recently acquired the Gastric Vest System™ through its acquisition of BarioSurg, Inc.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as expect," "plan," "anticipate," "could," "may," "intend," "will," "continue," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this release include statements regarding our plans and objectives for the ReNEW Study. These forward-looking statements are based on the current expectations of our management and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others: our limited history of operations; our losses since inception and for the foreseeable future; our limited commercial sales experience with our vBloc® System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; the competitive industry in which we operate; our ability to maintain compliance with the Nasdaq continued listing requirements; our ability to commercialize our vBloc® System; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for any modifications to our vBloc® System; physician adoption of our vBloc® System and vBloc® Neurometabolic 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; the cost and management time of operating a public company; 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 Exhibit 99.3 of our current report on Form 8-K filed July 26, 2017. 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.

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