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EnteroMedics Receives Approval for Gastric Vest System Clinical Study in Spain

ST. PAUL, Minn., July 31, 2017 /PRNewswire/ -- EnteroMedics Inc. (NASDAQ:ETRM), a developer of minimally invasive medical devices to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that the company has received approval from the Ministry of Health, Social Services, and Equality (MHSSE) in Spain through the Agency of Medicines and Medical Devices, and the CEIC Ethics Committee to initiate a clinical trial for the Gastric Vest™ System in Spain.



"We are thrilled to have reached this significant clinical milestone, which supports our plans for CE Mark approval and takes us one step closer to bringing our Gastric Vest product to market," said Dan Gladney, EnteroMedics President, Chief Executive Officer, and Chairman of the Board. "We believe that the Gastric Vest, which is designed to allow rapid excess weight loss over a short period of time through a minimally invasive, non-anatomy-changing procedure, will offer a novel solution for the obesity continuum of care."

EnteroMedics expects the safety and performance CE Mark study for the Gastric Vest to include a total of between 50-100 patients at up to four sites within the European Union. This approval by the MHSSE in Spain represents the first country approval for the Gastric Vest CE Mark trial. The clinical trial in Spain will be conducted under the supervision of Principal Investigator, Dr. Jordi Pujol Gebelli, and Co-Investigator, Dr. Amador Garcia Ruiz de Gordejuela at Hospital Universitari de Bellvitge, in Barcelona, Spain. Enrollment is expected to begin by early 2018.

About the Gastric Vest System

The Gastric Vest System (GVS) is an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in obese and morbidly obese patients. The device wraps around the stomach, emulating the effect of conventional weight-loss surgery, and enables gastric volume reduction without permanently changing patient anatomy.

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 our plans for CE Mark approval and bringing our Gastric Vest product to market, our belief that the Gastric Vest will offer a novel solution for the obesity continuum of care, and our expectation that the safety and performance CE Mark study for the Gastric Vest will include a total of 50-100 patients at up to four sites within the European Union with enrollment expected to begin by early 2018. 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 the annual report on Form 10-K filed March 8, 2017, the quarterly report on Form 10-Q filed May 15, 2017 and the 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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