# EnteroMedics Announces Regulatory Path Forward Following FDA Meeting

ST. PAUL, Minn., Jan 28, 2010 (BUSINESS WIRE) -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, announced today that, following a recent meeting with the U.S. Food and Drug Administration (FDA) to discuss the Company's EMPOWER(TM) study results and the regulatory process, the Company intends to submit an Investigational Device Exemption (IDE) application for a clinical trial to support a possible Premarket Approval (PMA) application for the next-generation Maestro(R) RC System in the treatment of morbid obesity.

"We had a constructive dialogue with the FDA about the regulatory steps necessary to move beyond the EMPOWER trial," stated Mark B. Knudson, Ph.D., President and Chief Executive Officer of EnteroMedics. "The Agency and the Company discussed regulatory direction for the Maestro System and the product approval process in support of our efforts to bring VBLOC therapy to market. As an outcome of this meeting, we will begin the next step in that regulatory process by preparing an IDE application for submission in the first quarter of 2010." Dr. Knudson added: "The Company remains fully committed to supporting the patients from the EMPOWER trial of the Maestro RF System."

**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 rechargable battery (EnteroMedics' next-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.

**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 12, 2009. 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.

SOURCE: EnteroMedics Inc.

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