EnteroMedics Announces Preliminary Results from Detailed Review of EMPOWER Study

Company to Host Conference Call November 12, 2009 8:00 AM EST

ST. PAUL, Minn., Nov 12, 2009 (BUSINESS WIRE) -- EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced preliminary findings from its ongoing detailed review of its EMPOWER(TM) study, a randomized, double-blind, controlled pivotal study designed to evaluate the safety and efficacy of the Maestro(R) System in the treatment of obesity. On October 2, 2009, the Company announced that the study did not meet its primary and secondary efficacy endpoints, as results in the control and treatment arms were statistically indistinguishable, while achieving all of its safety endpoints.

The ongoing detailed review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. The review further suggests that these effects were evident in both the treatment and control arms. The Company is continuing a comprehensive analysis of all clinical, statistical, and engineering data to understand this finding. Based on the analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC Therapy in human subjects.

The Company is informing patients and physicians of the following study findings:

- The EMPOWER study met all of its safety goals, including the finding that there were no therapy-related serious adverse events reported across the entire study population;
- Patients who met or exceeded the prescribed nine hours of daily device use (n=128, 51% of evaluated patients) averaged 10.9 hours of daily use and experienced an average excess weight loss (EWL) of 23.1% from implant by BMI method (18.3% from treatment initiation by Met Life method) in the treatment arm and 22.6% (BMI) from implant, (17.8% from initiation, Met Life) in the control arm at 12 months;
- Patients that did not meet the prescribed nine hours of daily device use (n=125) averaged 6.9 hours of daily use and experienced a mean EWL of 10.5% (BMI) from implant in the treatment arm (6.4% from initiation, Met Life) and 8.6% (BMI) in the control arm (4.6% from initiation, Met Life) at 12 months;
- For all patients (n=253), the average EWL at 12 months was 16.6% EWL (BMI) from implant (12.1% from initiation, MetLife) for the treatment arm and 16.4% EWL (BMI) from implant (12.0% from initiation, MetLife) for the control arm; and
- For those patients with a diagnosis of hypertension (n=110), a statistically significant reduction of systolic and diastolic blood pressure from baseline was observed, a result that will require follow-up study.

As of today, in accord with the study protocol, 252 patients remain in the EMPOWER study and are receiving VBLOC Therapy. Consistent with the study protocol, physicians are encouraging their patients to use the Maestro System for a minimum of the prescribed 9 hours per day.

"The EMPOWER study demonstrated a remarkable level of safety for an implanted medical device," added James W. Freston, M.D., Ph.D., Professor of Medicine and Clinical Pharmacology (*emeritus*),University of Connecticut Health Center and Chairman of the EMPOWER study Data Safety Monitoring Board.

"Results from the two arms of the EMPOWER study as well as from our previous VBLOC Therapy trials were consistent with each other, suggesting a pattern of positive clinical outcome when blocking the vagus nerve," said President and CEO Mark B. Knudson, Ph.D. "The apparent control arm effect, while unexpected, may be a scientifically important addition to our understanding of neuromodulation. We are taking steps to discuss the outcome of this study with the FDA to determine the appropriate regulatory path forward for the Maestro System as a treatment for morbid obesity."

The Company will discuss these findings in detail in a conference call and slide presentation today at 8:00 AM Eastern Standard Time.

Conference Call, Presentation and Webcast Details

EnteroMedics management will host a conference call and live webcast to discuss the detailed findings of its EMPOWER study November 12, 2009 at 8:00 AM Eastern Standard Time. The conference call may be accessed by dialing (888) 205-6702 for domestic callers and (913) 312-0665for international callers and providing passcode9194735. A replay of the call will be

available from November 12, 2009 at 10:00 AM Eastern Time through February 12, 2010 at 11:59 PM Eastern Time by dialing (888) 203-1112 for domestic callers and (719) 457-0820 for international callers and providing passcode 9194735.

The conference call will be accompanied by a slide presentation. The presentation and call will be webcast live and may be accessed by visiting EnteroMedics' website at www.enteromedics.com. Investors can access the webcast under "Press Room" in the "Investors" section of EnteroMedics' website. Please connect to EnteroMedics' website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. A replay of the webcast will also be available immediately after the conclusion of the presentation.

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. 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 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 an update to our October 2, 2009 press release and call 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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