EnteroMedics Announces PMA Application for VBLOC Therapy in Obesity Accepted for Review and Filing by FDA

The Associated Press

EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's Premarket Approval (PMA) application for approval of the Maestro® Rechargeable System's VBLOC® vagal blocking therapy as a treatment for obesity.

"The Maestro System holds the potential to fill a significant gap in the obesity treatment landscape, offering a unique, patient-friendly approach to addressing the long term challenges associated with obesity," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "FDA acceptance for filing of our PMA application is an important step toward this goal. We look forward to working closely with the FDA during the review process, continuing through an advisory committee panel and approval decision, as we prepare for U.S. commercialization of the Maestro System."

As previously announced, the FDA indicated in a pre-PMA meeting that, subject to a detailed review of the submitted data, the Company can anticipate presenting the PMA before a future FDA Advisory Committee panel. The accepted PMA application includes data from the Company's ReCharge Pivotal Trial, a prospective, double-blind, sham-controlled clinical trial involving 239 randomized patients (233 implanted) at ten sites in the United States and Australia.