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Viveve Submits Investigational Device Exemption to FDA to Conduct LIBERATE-U.S. Trial for Improvement of Stress Urinary Incontinence

ENGLEWOOD, Colo., Sept. 11, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today announced submission of an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for authorization to begin LIBERATE-U.S., a multicenter, randomized, double-blinded, sham-controlled trial to evaluate the safety and efficacy of the Company's proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women.

"The IDE submission for approval to conduct the LIBERATE-U.S. trial is an important milestone towards our objective to obtain regulatory clearances for CMRF for the treatment of SUI, a condition that we estimate affects approximately 25-30 million women worldwide," stated Scott Durbin, chief executive officer and director of Viveve. "This trial is also another reflection of our commitment to conducting sound scientific research and rigorous clinical trials that support the highest levels of evidence-based medicine to deliver safe and effective treatment of women's intimate health conditions using our proprietary CMRF technology. Pending authorization to proceed with the LIBERATE-U.S. trial, Viveve will have two ongoing multicenter SUI registration studies underway including our LIBERATE-International trial initiated in Canada in August 2018."

About the LIBERATE – U.S. Study
LIBERATE-U.S. is intended to be a randomized, double-blinded, and sham-controlled trial with enrollment of approximately 240 subjects at up to 25 study sites in the United States. Subjects will be randomized in a 2:1 ratio for active and sham treatments.

The proposed primary efficacy endpoint is the mean change from baseline in the standardized 1-hour Pad Weight Test, an FDA recommended endpoint in SUI clinical research. The study design also proposes to include evaluation of a three-day voiding diary, as well as multiple patient reported outcomes and safety follow-up throughout the study.

About Viveve
Viveve Medical, Inc. is a women's intimate health company passionately committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System, that delivers the Viveve treatment, incorporates clinically-proven cryogen-cooled, monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate robust neocollagenesis in a single in-office session.

International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in over 50 countries. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled study to assess improvement of sexual function in women following childbirth following an Investigational Device Exemption (IDE) application approval from the U.S. Food and Drug Administration (FDA) in March of 2018. If successful, this trial could support a marketing application for a new U.S. commercial indication. Currently, in the United States, the Viveve System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis.

Viveve has initiated LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of stress urinary incontinence in women and has submitted an IDE to the FDA for LIBERATE-U.S. The results of these two studies, if successful, could support marketing applications in the U.S, and additional countries around the world for this new commercial indication.

For more information visit Viveve's website atwww.viveve.com.

Safe Harbor Statement

All statements in this press release that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. While management has based any forward-looking statements included in this press release on its current expectations, the information on which such expectations were based may change. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties and other factors, many of which are outside of our control, which could cause actual results to materially differ from such statements. Such risks, uncertainties and other factors include, but are not limited to, the fluctuation of global economic conditions, the performance of management and our employees, our ability to obtain financing, competition, general economic conditions and other factors that are detailed in our periodic and current reports available for review at www.sec.gov. Furthermore, we operate in a highly competitive and rapidly changing environment where new and unanticipated risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. We disclaim any intention to, and undertake no obligation to, update or revise forward-looking statements to reflect events or circumstances that subsequently occur or of which we hereafter become aware.

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