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Viveve Announces Expansion of CMRF Technology Platform into Stress Urinary Incontinence Market

Company reports positive 12-month pilot study results and plans for two clinical registration studies to be conducted in Canada and the U.S.

ENGLEWOOD, CO -- (Marketwired) -- 01/31/18 -- Viveve Medical, Inc. (NASDAQ: VIVE) (the "Company"), a medical technology company focused on women's intimate health, today announced the expansion of its cryogen-cooled, monopolar radiofrequency (CMRF) technology platform into the stress urinary incontinence (SUI) market, the results from a recently completed 12-month pilot study and plans for two clinical registration studies to further assess the safety and efficacy of the Viveve System in the treatment of mild-to-moderate SUI.

Pilot Study 12-Month Results

A pilot study was conducted in Calgary, Alberta and included 10 patients who underwent treatment with Viveve's CMRF technology under a proprietary treatment protocol. Patients were followed for 12 months with safety and clinical results reported at 4, 6, 9 and 12 months post-treatment. Clinical results included composite scores from the validated ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form) and UDI-6 (Urogenital Distress Inventory-Short Form) outcome questionnaires. Results at 12 months (n=9) included an 89-100% responder rate (percentage of patients showing an improvement from baseline) and a 40-51% mean improvement at 12 months across both validated endpoints, respectively. No device-related safety issues were reported in any of the patients. The pilot study was conducted by Bruce Allan, PhD, MD, FRCS(C), founder and medical director of the Allan Centre.

"Our practice has treated women with vaginal laxity using Viveve's CMRF technology for more than five years. For SUI, the combined cooling and deep tissue capability of CMRF effectively targets the connective tissue that plays a critical role in the structural integrity of the vagina and the urinary system. In the pilot study, we found that SUI symptoms were significantly improved, providing strong support for the planned clinical registration studies and the potential to represent a major advance in the non-invasive treatment of SUI," said Dr. Allan.

"Based on the positive patient responses seen in the pilot study, including sustained reduction of symptoms at 12 months, Viveve has committed to move forward with two robust clinical registration trials to further assess the safety and efficacy of the Viveve System in the treatment of mild-to-moderate SUI," said Patricia Scheller, chief executive officer and director of Viveve, Inc. "The global market for the non-invasive treatment of SUI, estimated at $10 to $12 billion, represents a major market opportunity for Viveve."

International Registration Study Overview - LIBERATE (International)

LIBERATE (International) is intended to be a randomized, double-blind, sham-controlled study conducted in up to 10 sites in Canada and including up to 100 patients suffering from mild-to-moderate SUI. The primary efficacy endpoint is expected to be the 6-month change from baseline in the one-hour pad weight test and will include 12 months of safety follow-up, as well as assessments in other secondary endpoints. The Company is currently in the process of reviewing the protocol with Health Canada, and if the results of the study are positive, expects to use the outcome of this study for a registration filing in Canada and for CE Mark application in the EU for the temporary improvement of mild-to-moderate SUI symptoms.

U.S. Registration Study Overview - LIBERATE (U.S.)

LIBERATE (U.S.) is intended to be a randomized, double-blind, sham-controlled study in up to 25 centers across the U.S. and including up to 200 patients suffering from mild-to-moderate SUI. The primary efficacy endpoint is expected to be the 12-month change from baseline in the one-hour pad weight test and will include 12 months of safety follow-up, as well as assessments in other secondary endpoints. The Company anticipates submitting an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for the temporary improvement of mild-to-moderate SUI symptoms.

"SUI is very costly to treat and is a highly prevalent condition that affects millions of women worldwide. The expansion of our product portfolio into this indication demonstrates the unique versatility of our globally patented CMRF platform, as well as our continued commitment to scientific rigor and extensive clinical evidence," Ms. Scheller continued. "We are excited by the potential for a single, non-invasive treatment that can have a profoundly positive impact on women's quality of life in the estimated $10 to $12 billion global market for the treatment of SUI."

About Stress Urinary Incontinence

Stress urinary incontinence is a medical condition affecting an estimated 25-30 million women worldwide. It is a major challenge for women, particularly those who have experienced childbirth or are menopausal. Upwards of 55% of women with a previous vaginal delivery may exhibit symptoms of SUI. The need to use an external pad to absorb urine leakage associated with even normal activities such as coughing or laughing is unsatisfactory, inconvenient, often embarrassing and negatively impacts a woman's quality of life. Currently available and effective treatment options are extremely limited. Pelvic floor exercises (Kegels) and muscle strengthening products offer some benefit, but compliance and sustained benefit can be an issue. More aggressive approaches to manage SUI include pelvic surgery, slings and mesh. These options involve risk and recovery time and are a last resort for many patients. The ability to offer a minimally invasive, safe and effective treatment option for SUI using Viveve's CMRF technology would address an enormous unmet healthcare need for women.

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 GENEVEVE™ 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 from over 55 countries. Consistent with these approvals, Viveve is seeking an IDE from the FDA to conduct a pivotal study on use of the device for improvement in sexual function. Currently, in the United States, the Viveve System is cleared by the FDA for general surgical procedures for electrocoagulation and hemostasis.

InControl Products by Viveve are FDA cleared medical devices that treat stress, urge, and mixed incontinence conditions and products to improve pelvic floor strength. Viveve exclusively distributes InControl Medical's products to healthcare providers in the United States.

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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