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Viveve Announces Completion of Full Enrollment in Pivotal U.S. PURSUIT Trial for Stress Urinary Incontinence

Major milestone achieved in Company's advance toward a new U.S. SUI indication

ENGLEWOOD, CO / ACCESSWIRE / December 14, 2021 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that it has completed enrollment in its pivotal PURSUIT clinical trial to assess the efficacy and safety of the Viveve procedure in the treatment of stress urinary incontinence (SUI) in women. Positive results from the highly powered study could support an FDA approval for a new indication for Viveve's dual-energy, noninvasive, single session treatment in the U.S.

"We are very pleased to have completed enrollment in our landmark PURSUIT trial, which represents a major milestone and another example of our progress in advancing this important clinical program. The study has fully enrolled our target of 390 patients who met our inclusion criteria. Patient selection criteria in the PURSUIT trial is designed to provide us with the clear and robust data we need to evaluate a future regulatory filing," said Scott Durbin, Viveve's chief executive officer.

"We look forward to successfully completing the patient follow-up visits over the next 12 months and to releasing topline results, anticipated at the end of 2022. If positive, we anticipate filing our marketing application for FDA approval shortly thereafter." He concluded, "We have a high level of confidence in the strength of the PURSUIT study design and in our ability to execute our strategy to position this innovative technology for the final stages of regulatory review with the potential to bring a proven safe and effective treatment option to the millions of women living with SUI in the U.S."

U.S. PURSUIT Trial

PURSUIT is a randomized, double-blinded, sham-controlled trial with targeted enrollment of 390 subjects with moderate SUI (≥ 10ml - 50ml urine leakage on the 1-hour Pad Weight Test) at approximately 30 study sites in the U.S.

The primary efficacy endpoint is a comparison of the proportion of patients who experience greater than a 50% reduction in urine leakage compared to baseline on the standardized 1-hour Pad Weight Test at 12 months post-treatment versus the inert sham procedure. The study also includes several secondary endpoints, including: proportion of patients who experience a greater than 50% reduction in urine leakage on the standardized 1-hour Pad Weight Test at three and six months post-treatment; percentage change from baseline in the 1-hour Pad Weight Test at three, six, and 12 months; percent of subjects with no incontinence episodes at three, six, and 12 months post-treatment as assessed with the

three-day bladder voiding diary; and change from baseline in the MESA Questionnaire (Medical, Epidemiologic and Social Aspects of Aging), Incontinence Quality of Life (I-QOL), Patient Global Impression of Improvement (PGI-1) Questionnaire, and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) at three, six, and nine months post-treatment. Subject safety will be monitored throughout the study.

Stress Urinary Incontinence

Urinary incontinence is a loss of bladder control, often leading to uncontrollable urine leakage. This condition is often seen in women and older adults. One in three women experiences urinary incontinence, of which SUI is the most common form. Prevalence data suggest that 14 million women in the U.S. alone suffer daily from SUI episodes that can be associated with causes including coughing, sneezing, laughing, exercise, or vaginal childbirth.

About Viveve

Viveve Medical, Inc. is a medical technology company focused on women's intimate health. Viveve is committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve System incorporates CMRF technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session. In the U.S., the Viveve® System is cleared by the Food and Drug Administration (FDA) for use in general surgical procedures for electrocoagulation and hemostasis. International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in 50 countries.

For more information visit www.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 impact of the novel coronavirus termed COVID-19 on our clinical development and regulatory review and clearances and on the manufacturing, placements and patient utilization of our Viveve Systems, the performance of management and our employees, our ability to obtain financing, our evaluation of strategic alternatives, our ability to obtain approval or clearance for sale of our medical device for all indications sought, 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, unless required by law.

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