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Viveve Announces Completion of Pivotal US PURSUIT Trial for Female Stress Urinary Incontinence with Final 12-month Follow-up Visits Concluded

Topline results of the 12-month primary efficacy endpoint anticipated in January 2023

Positive results may support a de novo marketing application for a new U.S. indication for treatment of stress urinary incontinence in women

ENGLEWOOD, CO / ACCESSWIRE / December 15, 2022 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's health and treatment of female stress urinary incontinence, today announced the completion of final 12-month post-treatment follow-up visits in its landmark U.S. PURSUIT clinical trial for the treatment of stress urinary incontinence (SUI) in women. A total of 415 patients were enrolled in the trial, and 342 patients completed 12-month follow-up visits. A 17.6% loss-to-follow-up occurred, which is within the range anticipated for the trial. Upon completion of clinical data monitoring and analyses in the coming weeks, the company expects to present topline primary efficacy results from the PURSUIT trial in January 2023. If positive, the results may support a marketing application for a potential new SUI indication for Viveve's dual-energy, noninvasive, single-session treatment in the U.S.

"We are very pleased to announce the completion of all subject follow-up visits in our pivotal U.S. PURSUIT clinical trial. This major milestone was accomplished due to the tremendous efforts by our U.S. investigational sites and by the enormous dedication of our clinical and medical affairs team and the patients who participated in this trial," said Scott Durbin, Viveve's chief executive officer. "In the coming weeks, we will work towards database lock to perform the statistical analyses enabling us to present the topline results from the trial in early 2023. I'd like to thank the entire Viveve organization for their dedication during the two-year effort to complete this trial."

"Urinary incontinence (UI) is a condition that affects an estimated 28 million women in the U.S. alone. We estimate that nearly 15 million women suffer from SUI as the predominant UI condition. The need for a clinically proven, safe, noninvasive, office-based endovaginal procedure for women with SUI is considerable. We believe a positive PURSUIT trial outcome and subsequent FDA approval may provide Viveve with a significant commercial opportunity while bringing a proven effective treatment for SUI to millions of patients," concluded Mr. Durbin.

U.S. PURSUIT Trial

PURSUIT is a randomized, double-blinded, sham-controlled trial that enrolled 415 subjects with moderate SUI (≥ 10ml - 50ml urine leakage on the 1-hour Pad Weight Test) at

approximately 30 study sites in the U.S. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm received Viveve's SUI treatment, while subjects in the control arm received a sham treatment.

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 a sham treatment. The study also includes several secondary endpoints, including the 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 is monitored throughout the study.

About Viveve

Viveve Medical, Inc. (Viveve) is a women's health company focused on the treatment of female SUI. Based in Englewood, Colorado, the Company conducted the pivotal U.S. PURSUIT clinical trial using its novel, dual-energy treatment for SUI in women. The internationally patented Viveve® System incorporates CMRF technology to uniformly provide an endovaginal treatment that is non-ablative. 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 and/or urinary incontinence.

For more information visit 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, including, without limitation, implied and express statements regarding Viveve Medical, Inc.'s plans, timelines, or presumptions of results for the PURSUIT trial and the potential marketability and regulatory approval of the Viveve System for treatment of SUI. 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 timing, progress and results of our clinical trials, 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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