December 10, 2020

Viveve Announces FDA Approval of Proposed Amendments to Pivotal U.S. PURSUIT Trial Protocol

- ***Viveve authorized to increase trial size and introduce new patient selection criteria designed to improve study's power and data to support assessment of primary efficacy endpoint***
- ***Near-term launch planned for pivotal U.S. PURSUIT trial***

ENGLEWOOD, CO / ACCESSWIRE / December 10, 2020 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that the Company's proposed changes to the study design of its pivotal PURSUIT trial were approved by the U.S. Food and Drug Administration (FDA.) The Company submitted certain protocol amendments to the FDA in October intended to strengthen the overall study and improve the ability to use data from the study to support a clear assessment of the primary endpoint. Viveve plans to initiate the PURSUIT trial for the improvement of stress urinary incontinence (SUI) in women in the near future.

"We are pleased that the FDA has cleared the study design changes that we believe will significantly strengthen our pivotal PURSUIT trial. The protocol revisions were the result of guidance and input from our Clinical Advisory Board, upon review of the positive results from our recently reported SUI feasibility and preclinical studies," said Scott Durbin, Viveve's chief executive officer. "Most importantly, the study is now more likely to provide rigorous data based on better inclusion criteria and an increase in size to 390 enrolled subjects across 30 investigator sites in the U.S."

"We are excited to launch the PURSUIT trial soon and anticipate rapid enrollment. A positive readout from the PURSUIT trial will position Viveve for a potential SUI indication in the U.S.," added Mr. Durbin. "SUI is a medical condition that affects the daily quality of life of an estimated 25-30 million women worldwide, and the Viveve procedure has the potential to offer a safe and effective non-invasive treatment option."

U.S. PURSUIT Trial
PURSUIT is a randomized, double-blinded, sham-controlled trial with an intended enrollment of approximately 390 subjects at up to 30 study sites in the U.S. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm (260 subjects) will receive CMRF treatment (90J/cm2 RF and cryogen-cooling), while subjects in the control arm (130 subjects) will receive the Company's new inert sham treatment.

The primary efficacy endpoint of the PURSUIT Trial is a comparison of the proportion of patients who experience greater than 50% reduction in urine leakage on the standardized 1-hour Pad Weight Test at 12 months post-treatment versus the new sham procedure. The study also includes several secondary endpoints, including: proportion of patients who

experience greater than 50% reduction in urine leakage on the standardized 1-hour Pad Weight Test at three and six months post-treatment, change from baseline in the 1-hour Pad Weight Test at six and 12 months, and change from baseline in three-day bladder voiding diary, 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). Subject safety will be monitored throughout the study.

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 Cryogen-cooled Monopolar Radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session. In the United States, the Viveve® System is cleared by the 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 more than 50 countries.

Viveve continues to advance its clinical development program in SUI. The positive topline results reported from the 3-arm feasibility study and the preclinical study outcomes are intended to support the pivotal PURSUIT trial initiation and strengthen its potential to achieve its primary efficacy endpoint. Viveve received FDA approval of its IDE application to conduct the multicenter, randomized, double-blinded, sham-controlled PURSUIT trial for improvement of SUI in women in July 2020 and Agency approval of requested amendments to the IDE protocol in December 2020.

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 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, the outcome of our assessment of strategic alternatives, 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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