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Viveve Announces New Category III CPT Code for its Stress Urinary Incontinence Procedure

New code approved by American Medical Association and supported by key medical societies

Long-term pathway for potential reimbursement now established for Company's dual-energy noninvasive treatment for urethral hypermobility to improve stress urinary incontinence in women

ENGLEWOOD, CO / ACCESSWIRE / July 7, 2021 Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced that the American Medical Association (AMA) has issued a new Category III Current Procedural Terminology (CPT®) code for the Company's dual-energy procedure effective January 1, 2022. The new code establishes a pathway for potential reimbursement for Viveve's noninvasive treatment under evaluation in the PURSUIT trial to improve stress urinary incontinence (SUI) in women if approved by the U.S. Food and Drug Administration (FDA) for this indication.

The new Category III CPT code for Viveve's dual-energy procedure is defined as: endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissue surrounding the female bladder neck and proximal urethra for urinary incontinence. Category III CPT codes are AMA approved for new and developing technology, procedures and services. They allow for specific data collection and assessment over time for potential Category I qualification.

"The AMA approval of a new Category III CPT code is a significant milestone in our SUI clinical development and commercialization strategy. Issuance of the new code reflects the strong clinical evidence and potential benefit of our noninvasive, dual-energy procedure for improving SUI in women as reviewed by the AMA and supported by key medical specialty societies. Importantly, the new code establishes a pathway for potential reimbursement for the Company to pursue as we advance and complete our pivotal PURSUIT trial in the U.S.," said Scott Durbin, Viveve's chief executive officer. "Our strategic focus is to address the current unmet need of the estimated 11 million women in the U.S who suffer daily from SUI with an effective, noninvasive treatment option. Pending potential positive results from our PURSUIT trial and a potential new SUI indication in the U.S., we believe the Viveve procedure could become a preferred SUI treatment option that may be broadly covered by insurance in the future."

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 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. Recently reported FDA approved changes to the U.S. pivotal PURSUIT trial protocol are intended to strengthen the overall study and its potential to achieve its primary efficacy endpoint. Study changes including an increase in the trial's size and more strict patient selection criteria were a result of guidance from Viveve's Clinical Advisory Board upon review of positive results from the Company's SUI feasibility and preclinical studies. 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 FDA approval of its requested amendments to the IDE protocol as reported on December 10, 2020. Initiation of the trial was reported on January 21, 2021 and subject enrollment is underway. If positive, results from the PURSUIT trial may support a new SUI indication in the U.S.

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.

Viveve is a registered trademark of Viveve, Inc.

CPT is a registered trademark of the American Medical Association.

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