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Viveve Announces Notice of Allowance for Second U.S. Method Patent for Treating Female Stress Urinary Incontinence

Patent issuance further strengthens Viveve's intellectual property portfolio for the treatment of female stress urinary incontinence

ENGLEWOOD, CO / ACCESSWIRE / October 4, 2022/ Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's health and the treatment of female stress urinary incontinence (SUI), today announced the Company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. Patent Application 16/454,578 covering Viveve's unique dual-energy treatment to address SUI in women. The pending issuance of the new SUI patent further strengthens the Company's intellectual property portfolio in advance of the planned completion of its U.S. pivotal PURSUIT clinical trial by the end of the year and reporting of topline results in early 2023.

"We are pleased to announce the expansion of our SUI patent estate, particularly as we rapidly approach completion of our PURSUIT trial follow-up visits and plan to report topline results. This USPTO Notice of Allowance provides further validation of the method of use of our novel dual-energy technology designed for treating SUI in women," said Scott Durbin, Viveve's chief executive officer.

Viveve's dual-energy technology has demonstrated its ability to activate fibroblasts and initiate collagen formation in tissue in a non-invasive, painless and comfortable procedure. When applied to the areas surrounding the urethra, the technology's unique mechanism of action may strengthen and improve the function of connective tissues, improve vaginal structural integrity, and reduce urethral hypermobility, a leading cause of SUI in women.

"Currently, there is an enormous unmet need in the market for a non-invasive, safe, efficacious, and durable SUI treatment. We look forward to completing our pivotal PURSUIT clinical trial, which may support a new U.S. indication for the treatment of mild-moderate SUI in women if the results are positive," concluded Mr. Durbin.

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 is conducting a pivotal U.S. clinical trial called PURSUIT, using its novel, dual-energy treatment for SUI in women. The internationally patented Viveve® System incorporates Cryogen-cooled Monopolar Radiofrequency 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. Viveve's current commercial and market development efforts focus on the U.S. and Asia Pacific regions targeting urogynecology, urology, and gynecology core specialties.

Viveve received FDA approval of its Investigational Device Exemption (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 IDE protocol amendments in December 2020. The clinical trial was initiated in January 2021, and completion of subject enrollment was announced on December 14, 2021. Completion of subject follow-up visits is anticipated by the end of 2022, and topline results will be reported shortly thereafter. If positive, results from the PURSUIT clinical 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, including, without limitation, implied and express statements regarding Viveve Medical, Inc.'s plans, timelines, or presumptions of results for the PURSUIT trial, and the expected impact of the Notice of Allowance for U.S. Patent Application 16/454,578 on Viveve Medical, Inc.'s ability to market its technology for the treatment of SUI in women. 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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