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Viveve Announces FDA 510K Approval to Expand Manufacturing of Treatment Tips

Approval strengthens supply chain and reduces manufacturing costs for consumable component used with Viveve's Cryogen-cooled Monopolar Radiofrequency technology

ENGLEWOOD, CO / ACCESSWIRE / December 3, 2020/ Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced 510(k) clearance by the U.S. Food and Drug Administration (FDA) expanding manufacturing capacity for its consumable treatment tips used with the Company's Cryogen-cooled Monopolar Radiofrequency (CMRF) technology. Expanded manufacturing capacity will help Viveve continually meet market demand while reducing manufacturing costs.

"We are pleased that the FDA has approved the expansion of our consumable treatment tip manufacturing capabilities. In addition to significant reductions in tip manufacturing costs, the expansion strengthens our supply chain, reduces manufacturing risk, and positions us to support increases in treatment tip demand and utilization," said Scott Durbin, Viveve's chief executive officer. "Reducing costs and increasing operational and commercial efficiency are key initiatives as we continue to support our customers and prepare to launch our pivotal PURSUIT trial for improvement of stress urinary incontinence (SUI) in the U.S. in the near 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 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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