

July 14, 2020



Viveve Announces Clearance of Viveve 2.0 System in Thailand

Regulatory clearance expands availability of next-generation CMRF system in key Southeast Asia market

ENGLEWOOD, CO / ACCESSWIRE / July 14, 2020/ Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced it has received regulatory clearance from the Thai Food and Drug Administration for the company's next-generation Viveve 2.0 Cryogen-cooled Monopolar Radiofrequency (CMRF) system and consumable treatment tips.

"The approval of our Viveve 2.0 system by the Thai FDA represents an important milestone in our global regulatory and commercialization strategy. Thailand is one of the leading women's health and aesthetic medicine markets in Southeast Asia and an important addition to Viveve's expanding global commercial distribution network. We are pleased that the 2.0 System and consumable treatment tips are now available throughout the Asia Pacific region," said Scott Durbin, Viveve's chief executive officer.

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 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 indications in more than 50 countries.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI) and is conducting a short-term feasibility study under an Investigational Testing Application approved by the Canadian Ministry of Health. The feasibility study is a single-blind, three-arm study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment in order to capture short-term safety and effectiveness data on use of the Viveve System for the improvement of SUI in women. Subject enrollment in the study was completed in March 2020. Results of the SUI feasibility study are targeted for readout in late summer of 2020. If positive, the feasibility study results could support the initiation of the pivotal PURSUIT Trial. As announced on July 7, 2020, Viveve received FDA approval of its Investigational Device Exemption application to conduct the multicenter, randomized, double-blinded, sham-controlled PURSUIT Trial for improvement of SUI in women.

For more information visit Viveve's website at 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, 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.

Viveve is a registered trademark of Viveve, Inc.

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