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Viveve Announces Clearance of Next Generation 2.0 System in South Korea

Viveve 2.0 System and consumable treatment tips now commercially availablein U.S., European Union, China, and Korea

ENGLEWOOD, CO / ACCESSWIRE / December 10, 2019/ Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced registration clearance by the Korean Ministry of Food and Drug Safety for the company's next generation Viveve 2.0 cryogen-cooled monopolar radiofrequency (CMRF) system for use in general surgical procedures for electrocoagulation and hemostasis as well as for the treatment of vaginal laxity.

"We are pleased to have received our most recent clearance of the Viveve 2.0 System and its consumable treatment tips in South Korea, one of the largest and most influential global markets for women's aesthetic and intimate health procedures. JOYMG Co., Ltd., Viveve's exclusive distribution partner in South Korea, serves an established and growing base of physician customers who demand the latest advances in medical technology. We look forward to continuing our support of JOYMG in their efforts to expand awareness and adoption of Viveve's 2.0 System as a clinically proven safe and effective treatment to improve vaginal laxity," said Scott Durbin, Viveve's chief executive officer and director.

Clearance of the Viveve 2.0 System in South Korea represents the latest milestone in Viveve's ongoing regulatory strategy to expand the global commercial footprint of its next generation CMRF technology platform. The 2.0 System and consumable treatment tips are currently available in the U.S., European Union, China, and South Korea. Viveve continues its efforts to achieve additional regulatory clearances in markets around the world.

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.

Currently, in the United States, the Viveve System is cleared by the U.S. 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 over 50 countries. Viveve is conducting VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth. Completion of full 250 subject enrollment was announced in early March 2019. The top-line 12-month data read-out of the VIVEVE II trial is expected in April 2020. If successful,

VIVEVE II results could support a marketing application for a new U.S. commercial indication.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI) and plans to initiate a short-term feasibility study upon approval by the Canadian Ministry of Health of the investigational testing application submitted in August 2019. Following the positive yet inconclusive results of the LIBERATE-International trial, the proposed feasibility study will be a single-blind, three-arm, three-month study to compare Viveve's CMRF treatment to cryogen-only treatment and to 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. Results of the planned three-month feasibility study are targeted for read-out in April 2020. If positive, the results could be used to support Viveve's re-submission of its Investigational Device Exemption to the FDA for approval to conduct the LIBERATE-U.S. trial designed to evaluate the safety and effectiveness of the Viveve System for improvement of SUI in women. The results of these trials, if successful, could support marketing applications in the U.S. and over 30 countries around the world for this new commercial indication.

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 performance of management and our employees, our ability to obtain financing or pursue 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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