June 25, 2019

Viveve Announces FDA 510(k) Clearance of Viveve 2.0 Next Generation System in the U.S.

Company also announces expansion of distribution network targeting gynecology practices in the Middle East through partnership with Dansys Group

ENGLEWOOD, CO / ACCESSWIRE / June 25, 2019/ Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today announced 510(k) K190422 clearance by the U.S. Food and Drug Administration (FDA) 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.

"We are pleased to have received 510(k) clearance of the Viveve 2.0 System and its consumable treatment tips from the FDA, which is another important confirmation of the safety profile of our technology. This clearance is the most recent milestone in our ongoing regulatory strategy to expand the global commercial footprint of our next generation CMRF platform technology. In addition to bringing this innovative technology to patients in the U.S., this clearance can help streamline the regulatory pathway of our 2.0 technology in the Middle East and other important international markets," said Scott Durbin, Viveve's chief executive officer and director.

Distribution Partnership with Dansys Group

Viveve also announced establishment of a distribution agreement for the Viveve 2.0 System with Dansys Group LLC, a leading medical distributer in the Middle East. The agreement expands the distribution network for Viveve products throughout the Middle East.

"This new distribution partnership with Dansys Group will significantly expand our commercial footprint in the region through their large established customer base of gynecology practices, hospitals, and medical institutions. We look forward to working with an established and well-respected leader across the region in women's health," continued Mr. Durbin.

Mr. Jamil Maalouf, Dansys Group's chief executive officer, commented, "It is a privilege to enhance our portfolio and offer our medical specialty practice and hospital customers the evidence-based treatments for women's intimate health conditions that Viveve's unique CMRF technology provides. Dansys Group is committed to women's health innovation and recently hired Thomas B. McDermott as Vice President of Business Development. Thomas is a seasoned professional with a proven record of success in medical device sales and management, specifically with cutting-edge technology for women's health procedures. He is excited to partner with Viveve and lead the expanded adoption and utilization of this

innovative and proven-effective technology in the Gulf Region."

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 (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session.

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. If successful, VIVEVE II results could support a marketing application for a new U.S. commercial indication. Currently, in the United States, the Viveve® System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis.

Viveve has fully enrolled LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of stress urinary incontinence in women and plans to re-submit an IDE to the FDA for the LIBERATE-U.S. clinical trial after conducting certain safety testing. The results of these two 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, 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.

Investor Relations contacts:

Sarah McCabe
Stern Investor Relations, Inc.
(212) 362-1200
sarah@sternir.com

Amato and Partners, LLC
Investor Relations Counsel
admin@amatoandpartners.com

Media contact:

Kelly Wakelee
Berry & Company Public Relations
(212) 253-8881
kwakelee@berrypr.com

SOURCE: Viveve Medical, Inc.

View source version on accesswire.com:
https://www.accesswire.com/549772/Viveve-Announces-FDA-510k-Clearance-of-Viveve-20-Next-Generation-System-in-the-US