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Viveve Announces Positive Primary Efficacy Data from its SUI Feasibility Study and Positive Preclinical Outcomes that Support the Company's New Sham Tip for Pivotal PURSUIT Trial

- ***Achievement of primary efficacy endpoint in 3-arm SUI feasibility study demonstrates significant separation between CMRF treatment arm and inert sham arm***
- ***Positive in-vivo preclinical study validates new inert sham tip for use in upcoming pivotal PURSUIT Trial in U.S.***

ENGLEWOOD, CO / ACCESSWIRE / August 25, 2020 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced positive primary efficacy data from its three-arm, five-month Stress Urinary Incontinence (SUI) feasibility study to compare Viveve's Cryogen-cooled Monopolar Radiofrequency (CMRF) treatment and a cryogen-only sham treatment to an inert sham treatment for mild to moderate SUI in women. Additionally, the Company reported positive outcomes from an in-vivo preclinical study that was conducted to validate its new inert sham tip for use in the upcoming pivotal PURSUIT Trial in the U.S.

"We are extraordinarily pleased to report positive results from our 3-arm SUI feasibility study, as well as our in-vivo preclinical study. We believe the combined results from both of these studies support our thesis that the cryogen-cooling treatment tip, used as a sham treatment in our prior LIBERATE-International SUI trial, was likely producing a positive therapeutic effect. The fact that we now have a true inert sham treatment tip provides us more confidence that our upcoming pivotal PURSUIT Trial can achieve its primary efficacy endpoint and position Viveve for a potential SUI indication in the United States," said Scott Durbin, Viveve's chief executive officer.

SUI Feasibility Study and Topline Results
The 3-arm SUI feasibility study was a prospective, randomized and blinded clinical trial comparing the use of Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment in women with mild to moderate SUI. Three clinical trial sites in Canada enrolled a total of 36 patients on a 1:1:1 ratio to each of the three study arms. The primary efficacy endpoint, change from baseline in the standardized 1-hour Pad Weight Test at five months post treatment, was positively achieved.

STUDY ARM	Median Change from Baseline 1-Hour Pad Weight Test
CMRF ACTIVE (n=13)	**-9.5g (ml)**
CRYO ONLY SHAM (n=12)	-6.8g (ml)
INERT SHAM (n=11)	**-4.4g (ml)**

The median change from baseline in the active CMRF treatment group and the cryogen-only sham treatment group was -9.5 grams and -6.8 grams respectively, as compared to -4.4 grams in the inert sham treatment group. The study also assessed several secondary endpoints but showed no differentiation between groups. No device-related safety issues were reported.

In-vivo Preclinical Study and Results
In response to the inconclusive results from the company's LIBERATE International SUI trial, reported in July of 2019, Viveve conducted an in-vivo preclinical temperature and immunohistochemistry study to evaluate a new inert sham treatment tip. The Good Laboratory Practices (GLP) study was initiated in June of this year following several months of engineering, validation, and development work. The study assessed both in-vivo tissue temperature changes during treatment, and histopathology at 30-days post-treatment compared to baseline, in three parous ewes using Viveve's CMRF treatment tip (Active), cryogen-cooling only tip ("Old" sham treatment used in previous SUI study), and a new inert sham treatment tip. Histopathology of vaginal biopsies were performed and included use of *a*-smooth muscle actin (*a*-SMA) staining for fibroblast activation and formation. All tissue samples were evaluated by an independent and blinded pathologist.

The positive preclinical findings demonstrated both temperature and immunohistochemistry results that support the validity of the new inert sham tip to provide a true inert or placebo treatment. Only minor tissue temperature change (less than 2 degrees centigrade) was generated by the new inert sham tip and no fibroblast activation was shown through elevated *a*-SMA staining. In contrast, both the Active and cryogen-cooling sham tips demonstrated significant tissue temperature changes during treatment and increased fibroblast activation 30 days post-treatment.

U.S. PURSUIT Trial
As reported in July 2020, Viveve received U.S. Food and Drug Administration (FDA) approval of its Investigational Exemption Device (IDE) to conduct the pivotal PURSUIT SUI trial. The current FDA approved IDE trial is designed to be a randomized, double-blinded, sham-controlled 12-month trial with enrollment of approximately 240 subjects at up to 24 study sites in the U.S. Subjects will be randomized in a 2:1 ratio to CMRF treatment or to the new sham treatment.

The primary endpoint of the PURSUIT Trial is a comparison of the proportion of patients who experience a greater than 50% reduction in the standardized 1-hour Pad Weight Test at 12 months post treatment versus the new sham. The study also includes several secondary endpoints, including: proportion of patients who experience a greater than 50% reduction in the standardized 1-hour Pad Weight Test at 6 months post treatment, change from baseline in the 1-hour Pad Weight Test at 6 and 12 months, and change from baseline in 3-day bladder voiding diary, Urogenital Distress Inventory-6 (UDI-6), Incontinence Quality of Life (I-QOL), and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF). Subject safety will be monitored throughout the study.

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 SUI. The positive topline results reported from the 3-arm feasibility study and the preclinical study outcomes are intended to support the initiation of the pivotal PURSUIT Trial and strengthen its potential to achieve its primary efficacy endpoint. 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 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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