

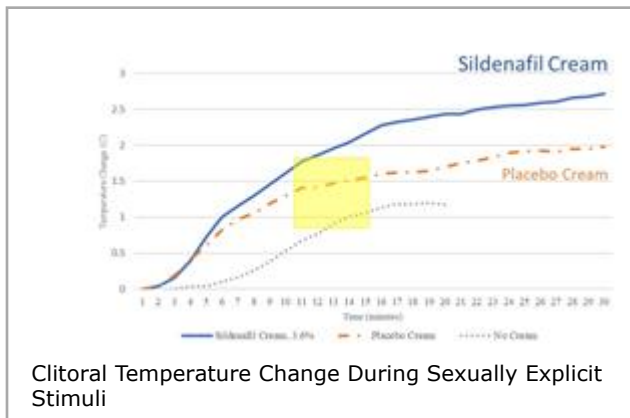


Daré Bioscience and Strategic Science & Technologies Announce Presentation of Positive Findings from Thermography Clinical Study of Sildenafil Cream, 3.6% in Healthy Women at the Sexual Medicine Society of North America Conference

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Sildenafil Cream, 3.6% produced statistically significant and clinically meaningful responses compared to placebo cream, further validating the potential for Sildenafil Cream, 3.6% to be an on-demand treatment for FSAD.

SAN DIEGO, Oct. 28, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, and Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced a poster presentation at the Sexual Medicine Society of North America 20th Annual Fall Scientific Meeting, which took place in Nashville, Tennessee, October 24-27, 2019. Daré, in collaboration with SST, is developing Sildenafil Cream, 3.6% as a potential treatment for female sexual arousal disorder (FSAD).



Sue Goldstein, CCRC, AASECT-CSE, Clinical Research Manager at San Diego Sexual Medicine, presented positive findings from a double-blind, placebo-controlled, 2-way crossover study that used thermography to assess the pharmacodynamics of Sildenafil Cream, 3.6% in healthy women.

"The study findings showed statistically significant increases in genital temperature, a surrogate for genital blood flow, and self-reported arousal response within thirty minutes of application of Sildenafil Cream when compared to placebo, demonstrating that Sildenafil Cream elicits a quantifiable, rapid genital response," said the principal investigator for the study, Dr. Irwin Goldstein, Director of Sexual Medicine at Alvarado Hospital and Director of San Diego Sexual Medicine. "There are currently no FDA-approved products for the treatment of FSAD, so these findings are encouraging and demonstrate the potential of Sildenafil Cream to become an important new therapy for women with FSAD."

FSAD is a condition characterized primarily by an inability to attain or maintain sufficient genital arousal during sexual activity. Sildenafil is the active ingredient in Viagra®, the orally administered treatment for erectile dysfunction (ED) in men. As with ED in men, FSAD in women is associated with insufficient blood flow to the genitalia. Sildenafil Cream, 3.6%, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina, is designed to increase genital blood flow and provide improvements in the female genital arousal response while avoiding systemic side effects commonly observed with oral formulations of sildenafil. Market research suggests that 33% of women in the U.S., ages 21 to 60, experience symptoms of low or no genital arousal during sexual activity, and 16%, or approximately 10 million women, are distressed and are seeking a solution to improve their condition.

As [previously announced](#), the study was designed to evaluate the feasibility of thermography to assess the pharmacodynamics of

Sildenafil Cream. Six women aged 25 to 55 without sexual dysfunction were recruited to participate, the median age was 36.3 years. All participants passed a comprehensive medical screening at Visit 1 to be eligible to participate in Visits 2 and 3, which had a 2-way crossover design. Genital and thigh temperature (non-genital control) were remotely recorded during each visit using the FLIR® system Thermos Vision A320 thermal imaging camera and FLIR Research IR v4.4 software.

Genital temperature data were analyzed using repeated measures **analysis of variance** (ANOVA), with time in minutes as the repeated measure and cream condition as the independent variable. There were statistically significant differences between Sildenafil Cream and placebo cream, as well as the no cream condition. As shown in Figure 1 below, Sildenafil Cream produced a statistically significant greater linear slope during minutes 11-15 of the sexually explicit film as compared to placebo cream.

The study is part of a comprehensive clinical development and regulatory plan for Sildenafil Cream that Daré intends to implement in collaboration with SST. The development plan includes assessing the safety and efficacy of Sildenafil Cream in Phase 2b and Phase 3 clinical studies.

“The results of this study reaffirm our commitment to develop a first-in-category product to address a persistent unmet need in women’s health,” said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. “FSAD is a challenging and highly prevalent condition with no FDA-approved therapies currently available. We are leveraging a well-established PDE5 inhibitor, sildenafil, and delivering it in a novel way to potentially offer women a new solution to a very distressing condition.”

A copy of the poster presented at the Sexual Medicine Society of North America Conference is available on the Events and Presentations page of Daré’s investor relations website (<http://ir.darebioscience.com>).

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women’s health. The company’s mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré’s product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a hormone-free, monthly contraceptive intravaginal ring; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré’s full portfolio of women’s health product candidates, and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations website (<http://ir.darebioscience.com>), SEC filings, press releases, public conference calls and webcasts. Daré will use these channels to distribute material information about the company, and may also use social media to communicate important information about the company, its finances, product candidates, clinical trials and other matters. The information Daré posts on its investor relations website or through social media channels may be deemed to be material information. Daré encourages investors, the media, and others interested in the company to review the information Daré posts on its investor relations website (<https://darebioscience.qcs-web.com/>) and to follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted on the investor relations page of the company’s website mentioned above.

Forward-Looking Statements

Daré cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the potential of Sildenafil Cream, 3.6% to become the first FDA-approved treatment option for FSAD, the usefulness of the thermography study to clinical development and potential regulatory approval of Sildenafil Cream, 3.6% for FSAD, and Daré’s commitment to continued clinical development of Sildenafil Cream, 3.6%. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Daré’s actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, without limitation, risk and uncertainties related to: Daré’s ability to raise additional capital when and as needed, to advance its product candidates; Daré’s ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré’s product candidates in a timely manner; Daré’s ability to conduct and design successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient safety and efficacy of its product candidates; the risk that promising results in pre-clinical studies may not be replicated when a product candidate is tested in human subjects; Daré’s ability to retain its licensed rights to develop and commercialize a product candidate; Daré’s ability to satisfy the monetary obligations and other requirements in connection with its exclusive, in-license agreements covering the critical patents and related intellectual property related to its product candidates; developments by Daré’s competitors that make its product candidates less competitive or obsolete; Daré’s dependence on third parties to conduct clinical trials and manufacture clinical trial material; Daré’s ability to adequately protect or

enforce its, or its licensor's, intellectual property rights; the lack of patent protection for the active ingredients in certain of Daré's product candidates which could expose its products to competition from other formulations using the same active ingredients; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; and disputes or other developments concerning Daré's intellectual property rights. Daré's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of Daré's risks and uncertainties, you are encouraged to review its documents filed with the SEC including Daré's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Daré undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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Source: Daré Bioscience

A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/e23cbf45-4b09-4330-8a60-30af435cddd4>



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