



Daré Bioscience Announces Publication in The Journal of Sexual Medicine of Positive Safety Findings from the Phase 2b RESPOND Clinical Study of Sildenafil Cream, 3.6%

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Published data show that topical Sildenafil Cream, 3.6% was safe and well tolerated by women and their partners across 1,357 sexual experiences.

Use of topical Sildenafil Cream, 3.6% did not produce the common side effects of headache and flushing associated with oral sildenafil use in women.

SAN DIEGO, Aug. 26, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today announced that safety and tolerability data from the exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6%, an investigational topical cream formulation of sildenafil being developed as an on-demand treatment for female sexual arousal disorder (FSAD), has been published by *The Journal of Sexual Medicine*.

Publication Details:

Thurman, et al. "Safety of topical sildenafil cream, 3.6% in a randomized, placebo-controlled trial for the treatment of female sexual arousal disorder." *The Journal of Sexual Medicine*, 2024, 1-7. <https://doi.org/10.1093/jsxmed/qdae089>

"We were very pleased to see a favorable safety and tolerability profile from both patients and their partners in this study," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "This is a particularly robust safety dataset since it includes assessments of both the participants and their partners."

"Topical sildenafil cream was well tolerated in this study," said Dr. Annie Thurman, MD, FACOG, lead author of the publication and Medical Director at Daré Bioscience. "Because oral sildenafil has known hypotensive effects, we were watching for related side effects such as headache, flushing, nausea, and dizziness. In the RESPOND study with our topical application, however, we did not see these effects, likely due to the hundred-fold lower systemic exposure as compared to oral dosing of sildenafil."

The exploratory Phase 2b RESPOND study evaluated the systemic and local genital safety of Sildenafil Cream, 3.6%, or Sildenafil Cream, among healthy premenopausal women with FSAD and their sexual partners over a 12-week treatment period. Study data demonstrate that Sildenafil Cream was safe and well tolerated among users and their exposed sexual partners. Safety was assessed among participants and their sexual partners after 1,357 and 1,160 sexual experiences in which Sildenafil Cream or placebo cream were used, respectively. Limitations of the safety data are that the study was not powered to demonstrate statistically significant differences in the frequency and incidence of treatment-emergent adverse events. The exploratory Phase 2b RESPOND study was specifically designed to identify the patient population that experienced the most meaningful improvement from Sildenafil Cream and the questions to ask them, or the patient-reported outcome (PRO) measures, that best reflect that improvement. The patient population and the endpoints proposed by Daré to the U.S. Food and Drug Administration (FDA) for Phase 3 clinical development were those where Daré's exploratory post-hoc analyses of the Phase 2b study data showed that Sildenafil Cream demonstrated statistically significant and meaningful patient improvement. Daré continues to interact with the FDA on the development program for Sildenafil Cream as a treatment for female sexual arousal disorder and is concurrently performing operational activities to support the planned Phase 3 program.

As previously announced, efficacy data from the Phase 2b RESPOND study were published in *Obstetrics & Gynecology*, the official publication of the American College of Obstetricians and Gynecologists. The journal article, entitled "Preliminary Efficacy of Topical Sildenafil Cream for the Treatment of Female Sexual Arousal Disorder: A Randomized Controlled Trial," can be found in the August 2024 issue of *Obstetrics & Gynecology* 144(2):p 144-152, and is available online at https://journals.lww.com/greenjournal/fulltext/2024/08000/preliminary_efficacy_of_topical_sildenafil_cream.4.aspx.

About FSAD and Sildenafil Cream, 3.6%

FSAD, as described in the DSM-IV, is a condition characterized primarily by a persistent or recurrent inability to attain or maintain sufficient genital arousal (an adequate lubrication-swelling response) during sexual activity, frequently resulting in distress or interpersonal difficulty. FSAD is clinically analogous to erectile dysfunction (ED) in men. As with ED in men, FSAD is associated with insufficient blood flow to the genitalia.

Sildenafil, a phosphodiesterase-5 (PDE-5) inhibitor, is the active ingredient in a tablet for oral administration currently marketed under the brand name Viagra® for the treatment of ED in men. Sildenafil Cream is an investigational, proprietary cream formulation of sildenafil designed for topical administration to the vulvar-vaginal tissue on demand to increase genital blood flow and provide improvements in the female genital arousal response, while avoiding systemic side effects observed with oral formulations of sildenafil.

Market research suggests that 16% of women in the U.S. ages 21 to 60, or approximately 10 million women, are distressed from experiencing symptoms associated with FSAD, including lack of or low sexual arousal, and are actively seeking solutions to improve their condition. In comparison, the prevalence of complete ED in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing 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 prioritize women's health and well-being, expand treatment

options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility.

The first FDA-approved product to emerge from Daré's portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. To learn more about XACIATO, Daré's full portfolio of women's health product candidates, and Daré's mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma 2022. In 2023, Daré's CEO was honored as one of Fierce Pharma's Most Influential People in Biopharma for Daré's contributions to innovation and advocacy in the women's health space. Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

Daré may announce material information about its finances, product and product candidates, clinical trials and other matters using the Investors section of its 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 and 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 in the Investors section of its website and to follow these X (formerly Twitter) accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted in the Investors section of Daré's website.

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," "objective," or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements relating to Sildenafil Cream's potential as a safe, well-tolerated and effective therapy for FSAD, Daré's plans for continued clinical development of Sildenafil Cream, including Phase 3 clinical trial design, the potential for Sildenafil Cream to be the first FDA-approved treatment for FSAD, and the potential market opportunity for Sildenafil Cream. As used in this press release, the description of a product candidate as "first-in-category" is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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, risks and uncertainties related to: Daré's ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy and continue as a going concern; the risk that data from the Phase 2b RESPOND study may not be predictive of positive results of any future clinical study; the risk that the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré's interpretation of or conclusions regarding the study data; the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product candidate; Daré's ability to design and conduct 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; Daré's dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré's product or product candidates, if approved, to gain market acceptance or obtain adequate coverage or reimbursement from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a product or 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 and product candidates; 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; product liability claims; governmental investigations or actions relating to Daré's product or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents or similar events that compromise Daré's technology systems or those of third parties on which it relies and/or significantly disrupt Daré's business; 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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