Daré Bioscience Announces Publication in Obstetrics & Gynecology of Phase 2b Study Efficacy Results of Topical Sildenafil Cream, 3.6% for the Treatment of Female Sexual Arousal Disorder

06-24-2024 at 8:00 AM EDT

Phase 2b study demonstrated topical Sildenafil Cream, 3.6% improved outcomes among women with female sexual arousal disorder (FSAD), particularly in an exploratory subset of women with FSAD with or without concomitant decreased desire

There are currently no FDA-approved therapies for FSAD

SAN DIEGO, June 24, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today announced the publication in *Obstetrics & Gynecology*, the official publication of the American College of Obstetricians and Gynecologists (ACOG), of the Phase 2b study efficacy results of topical Sildenafil Cream 3.6% (Sildenafil Cream), which is being developed for the treatment of female sexual arousal disorder (FSAD).

The Phase 2b clinical study was designed as an exploratory, multi-center, double-blind, placebo-controlled study to evaluate the preliminary efficacy and safety of Sildenafil Cream, 3.6% in premenopausal patients with FSAD. Topical Sildenafil Cream improved outcomes among women with FSAD, most significantly in a subset of women both with and without concomitant decreased desire. In an exploratory post-hoc analysis of this group, topical Sildenafil Cream significantly increased sexual arousal sensation and reduced sexual distress, as well as improved desire and orgasm.

“Arousal disorder represents a significant unmet need, impacting approximately 20% of women in the U.S.[1],” said Dr. Annie Thurman, MD, FACOG, Medical Director at Daré Bioscience. “Publication of this efficacy manuscript in an important peer-reviewed medical journal validates the importance of these findings for the field, shedding light for the first time on which women with FSAD and symptoms can be expected to benefit most from the increased genital blood flow that Sildenafil Cream mechanistically provides, and further underscores the potential of Sildenafil Cream to address the unmet need and improve outcomes for women with FSAD.”

“We are so pleased that this manuscript has been accepted in the official publication of the American College of Obstetricians and Gynecologists,” added Sabrina Martucci Johnson, President and CEO of Daré Bioscience. “It truly underscores the importance of these groundbreaking data and can hopefully continue to advance the field with the insights these data provide into this patient population as well as the patient reported outcome measures that are most meaningful to them in measuring their improvement.”

Daré Bioscience previously announced a positive end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) supporting advancement of Sildenafil Cream for the treatment of FSAD and has continued to interact with the FDA as the FDA reviews, specifically, the data generated on the proposed endpoints to take forward into Phase 3 development. The FDA has indicated that it aims to complete its review of the Phase 2b study data and provide comments this quarter on the proposed primary and secondary patient reported outcome endpoints for the planned Phase 3 pivotal trials of Sildenafil Cream to support potential product registration and labeling.

The in-press accepted manuscript, entitled *“Preliminary Efficacy of Topical Sildenafil Cream for the Treatment of Female Sexual Arousal Disorder: A Randomized Controlled Trial”* is available online at https://journals.lww.com/greenjournal/fulltext/9900/preliminary_efficacy_of_topical_sildenafil_cream.1101.aspx.

About FSAD and Sildenafil Cream, 3.6%

FSAD, as described in the DSM-IV, is a condition characterized as 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, and, of the various types of female sexual dysfunction disorders, 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 and effective therapy for FSAD, Daré's plans for continued clinical development of Sildenafil Cream, the timing of FDA comments on Sildenafil Cream Phase 3 clinical study design, the potential for Sildenafil Cream to be the first FDA-approved treatment of FSAD, and the potential market opportunity for Sildenafil Cream. 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 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 impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; 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.

Contacts:

Media and Investors on behalf of Daré Bioscience, Inc:
Camilla White / Simona Kormanikova
Dentons Global Advisors
DareBioscience@dentonsglobaladvisors.com / 1.212.466.6450

Source: Daré Bioscience, Inc.

---

[1] Laumann EO, Michael RT and Gagnon JH. A political history of the national sex survey of adults. *Fam Plann Perspect* 1994; 26: 34-38.

Witherow-Parkanyi M. Female sexual interest/arousal disorder: history of diagnostic considerations and their implications for clinical practice. *Psychiatr Hung* 2022; 37: 133-149.

Jayne C and Gago BA. Diagnosis and treatment of female sexual arousal disorder. *Clin Obstet Gynecol* 2009; 52: 675-681. DOI: 10.1097/GRF.0b013e3181bf4982.

Source: Daré Bioscience, Inc.