Daré Bioscience to Present at the International Society for the Study of Women's Sexual Health (ISSWSH) Annual Meeting

02-22-2024 at 8:00 AM EST

Data to be presented demonstrate increased frequency of sexual events with Sildenafil Cream, 3.6% use in the Phase 2b RESPOND clinical study, as well as improvement in multiple aspects of the sexual experience

Continuing to work toward Phase 3 pivotal study

There are no FDA-approved treatments for female sexual arousal disorder

SAN DIEGO, Feb. 22, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced that additional data from the exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% (Sildenafil Cream) in women with female sexual arousal disorder (FSAD) will be presented at the upcoming International Society for the Study of Women's Sexual Health (ISSWSH) Annual Meeting. These data include efficacy results across multiple endpoints in the proposed Phase 3 study population.

Presentation Details

Poster 1:	*Sexual Experiences in an Exploratory, Phase 2b, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Sildenafil, 3.6% Cream for the Treatment of Female Sexual Arousal Disorder* https://www1.statusplus.net/misc/posters/isswsh/annual2024/search/poster/92?redirect=pm
Poster 2:	*Impact of Enrollment Diagnosis on Efficacy Endpoints in an Exploratory, Phase 2b, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Sildenafil Cream, 3.6% for the Treatment of Female Sexual Arousal Disorder* https://www1.statusplus.net/misc/posters/isswsh/annual2024/search/poster/93?redirect=pm
Poster 3:	*Female Sexual Distress in an Exploratory, Phase 2b, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Sildenafil Cream, 3.6% for the Treatment of Female Sexual Arousal Disorder* https://www1.statusplus.net/misc/posters/isswsh/annual2024/search/poster/94?redirect=pm
Session:	Poster Session 8 - Novel Drugs, Methods and Technologies (non-CME)
Presenter:	Andrew T. Goldstein, MD
Date / Time:	Saturday, February 24, 2024; 10:05 a.m. – 10:35 a.m. PST
Location:	Long Beach, CA

"The data from the Phase 2b RESPOND study demonstrate that Sildenafil Cream treatment reduced sexual distress across multiple measures in a clinically meaningful way," said Dr. Andrew Goldstein, Medical Advisor for Daré Bioscience and former President of ISSWSH. "The results highlight specific endpoints with the strongest responses including arousal sensation, desire, orgasm, as well as stress, guilt, and embarrassment about the sexual dysfunction. Most importantly, based on these responses, we've identified the study population that will likely demonstrate the most significant benefit from Sildenafil Cream treatment, which consists of healthy premenopausal women with female sexual arousal disorder, including those who suffered from a lack of sexual desire due to their decreased arousal."

Dr. Goldstein will also present data on sexual experiences from the study, which showed that Sildenafil Cream users had more sexual experiences and more solo sexual experiences than placebo users. Notably, Sildenafil Cream enhanced solo, unpartnered sexual experiences, which represented approximately 1 in 5 sexual events in the Phase 2b RESPOND study.

"We are excited to share additional data from this groundbreaking study in one of the leading forums for scientific research on female sexual dysfunction," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "This is an area of significant unmet need and the improvements demonstrated in the Phase 2b RESPOND study in the target population we want to take forward to the Phase 3 program provide an important step towards advancing this potential first-in-category treatment for this challenging condition. We will continue to work with the FDA to align on and finalize the planned Phase 3 program for Sildenafil Cream."

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 erectile dysfunction (ED) in men. Sildenafil Cream is an investigational, proprietary topical cream formulation specifically designed to be used on-demand at the time of sexual activity to increase blood flow to the genital tissue in women. If development is successful, Sildenafil Cream has the potential to be the first product approved by the U.S. Food and Drug Administration (FDA) to treat FSAD.

Daré Bioscience previously announced a positive end-of-Phase 2 meeting with the FDA supporting advancement of Sildenafil Cream for the treatment of FSAD. The FDA recently confirmed that it aims to complete its review of the Phase 2b RESPOND study data and provide comments within the second quarter of 2024 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.

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, and, of the various types of female sexual dysfunction disorders, FSAD is most analogous to 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, including Phase 3 study design details and anticipated timing, the potential for Sildenafil Cream to be the first FDA-approved treatment for 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; 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 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 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 data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; 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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