Daré Bioscience to Present at the Sexual Medicine Society of North America (SMSNA) 24th Annual Fall Scientific Meeting

11-13-2023 at 8:00 AM EST

SAN DIEGO, Nov. 13, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, and its collaborator Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced that an overview of the preliminary efficacy findings 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 Sexual Medicine Society of North America (SMSNA) 24th Annual Fall Scientific Meeting. This will be the first time these findings from the Phase 2b RESPOND study, demonstrating improvement in multiple facets of sexual dysfunction, will be presented at a scientific conference.

Presentation Details

Abstract:	Preliminary Efficacy of Sildenafil Cream, 3.6% in an Exploratory, Randomized, Placebo-Controlled, Phase 2b Trial for the Treatment of Female Sexual Arousal Disorder
Session:	Innovation & Sexual Medicine (non-CME)
Presenter:	Andrew T. Goldstein, MD
Date / Time:	Saturday, November 18, 2023; 1:30 p.m. – 3:30 p.m. PST
Location:	San Diego, CA

"The comprehensive Phase 2b RESPOND study data represent an important milestone in the field of female sexual dysfunction," said Dr. Andrew Goldstein, Medical Advisor for Daré Bioscience and former President of The International Society for the Study of Women's Sexual Health (ISSWSH). "The results I will discuss highlight important attributes and meaningful improvements across the women who benefitted from Sildenafil Cream treatment most significantly in this study, which included women with not only female sexual arousal disorder but also those who suffered from a lack of sexual desire along with decreased arousal."

"The findings from this study in arousal, desire, and orgasm among the women treated with Sildenafil Cream support the potential of Sildenafil Cream to provide improvements across the sexual experience continuum, as has been seen among men treated for erectile dysfunction with sildenafil products," said James A. Simon, MD, CCD, NCMP, IF, FACOG, Clinical Professor, Obstetrics and Gynecology, George Washington University and President and Medical Director of IntimMedicine Specialists®, as well as former President of ISSWSH, and former President of The Menopause Society (formerly known as The North American Menopause Society, or NAMS).

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 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 any form of arousal disorder in women.

"To date, there have been no FDA-approved treatments for female sexual arousal disorder, a condition which significantly compromises a woman's ability to have a pleasurable sexual experience," commented Dr. Sheryl Kingsberg, Division Chief of Behavioral Medicine, Department of OBGYN, University Hospitals Cleveland Medical Center, Ohio, and former President of ISSWSH. "These additional data from the Phase 2b RESPOND study, which demonstrated improvements in a broader population of women, underscore the meaningful potential for Sildenafil Cream in women's sexual health. There is a critical unmet need for a safe, effective and 'on demand' solution to difficulties with sexual arousal."

Market research suggests that approximately 20 million women in the United States, aged 21-60, experience symptoms of low or no sexual arousal, and approximately 10 million women are considered distressed and actively seeking treatment.

About FSAD and FSIAD

Female sexual arousal disorder (FSAD) and female sexual interest/arousal disorder (FSIAD), should be distinguished from other female sexual disorders characterized in the Diagnostic and Statistical Manual (DSM), such as orgasmic disorder (anorgasmia) and hypoactive sexual desire disorder (HSDD), which is characterized as lack or absence of sexual fantasies and desire for sexual activity for some period of time.

FSAD, as described in the fourth edition (text revision) of the DSM (DSM-IV-TR), 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 most analogous to erectile dysfunction (ED) in men. As with ED in men, FSAD is associated with insufficient blood flow to the genitalia.

FSIAD is characterized in the fifth edition of the DSM (DSM-5) as lack of, or significantly reduced, sexual interest and/or arousal for at least six months and the symptoms must be severe enough to cause clinically significant distress. A woman must have three of the following six symptoms in order to receive an FSIAD diagnosis: absent or reduced interest in sexual activity; absent or reduced sexual thoughts or fantasies; no or reduced initiation of sexual activity, and typically unreceptive to a partner's attempts to initiate; absent or reduced sexual excitement or pleasure in almost all or all sexual encounters; absent or reduced sexual interest/arousal in response to any internal or external sexual cues; and absent or reduced genital or

non-genital sensations during sexual activity in all or almost all sexual encounters. FSIAD can be lifelong or acquired, range from mild to severe, and may be generalized or situational.

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.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel 2% is 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. 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 to treat female sexual arousal disorder (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; 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 and/or FSIAD, the potential indications and usage of Sildenafil Cream, if approved, the significance of the findings from the exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, Daré's plans for continued clinical development of Sildenafil Cream, the potential primary endpoints and patient population to be evaluated in pivotal clinical studies of Sildenafil Cream, the potential for Sildenafil Cream to be the first FDA-approved treatment for any form of sexual arousal disorder in women, 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 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 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.

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