Daré Bioscience Announces Additional Positive Data from Exploratory Phase 2b RESPOND Study of Sildenafil Cream, 3.6% in Women

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Sildenafil Cream Demonstrated Statistically Significant Improvement in Sexual Desire, an Exploratory Endpoint; Improvements in Arousal Lubrication, Orgasm and Sexual Desire Seen in the Sildenafil Cream Group Persisted through End of Study

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

Webinar to be held Tuesday, July 11, 2023, at 4:30 p.m. EDT will include presentations by Daré management and key opinion leaders in sexual medicine

SAN DIEGO, July 11, 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 additional positive data from the exploratory Phase 2b RESPOND study evaluating topical Sildenafil Cream, 3.6% (Sildenafil Cream) as a treatment for female sexual arousal disorder (FSAD). Additional data reported today support continued clinical development of Sildenafil Cream to evaluate its potential to treat FSAD and/or female sexual interest/arousal disorder (FSIAD). Specifically, an exploratory endpoint regarding sexual desire demonstrated a statistically significant improvement from baseline to the 8-week mark after randomization in women in the intent to treat (ITT) population who used Sildenafil Cream compared to placebo, at P value = 0.022. The improvement in sexual desire at the 8-week mark compared to baseline in the Sildenafil Cream ITT group persisted through 12 weeks post-randomization (end of study).

“In this study, improvement was seen in arousal and orgasm, as well as sexual desire. Such changes are consistent with those seen in men treated for erectile dysfunction. Namely, improve one’s arousal, and ultimately orgasm, and desire increases as well. An FDA-approved option like this for women would provide improvements across the sexual experience continuum, as men have had for over 25 years,” commented James A. Simon. M.D., CCD, NCMP, IF, FACOG, Clinical Professor, Obstetrics and Gynecology, George Washington University and President and Medical Director of IntimMedicine Specialists®, as well as Past President of The International Society for the Study of Women's Sexual Health (ISSWSH), and Past President of The North American Menopause Society (NAMS).

Based on data from the exploratory Phase 2b RESPOND study, demonstrating improvement in multiple facets of female sexual dysfunction, and because there is no FDA-approved product for FSAD, as described in the fourth edition of the Diagnostic and Statistical Manual (DSM-IV), or for FSIAD, as described in the fifth edition of the Diagnostic and Statistical Manual (DSM-5), Sildenafil Cream has the potential to be a first-in-category product.

Daré will host a virtual Key Opinion Leader (KOL) webinar on Tuesday, July 11, 2023, at 4:30 p.m. EDT to review data from the exploratory Phase 2b RESPOND clinical study. In addition to the data presentation, the KOL webinar will include discussions on the diagnosis and treatment of FSAD and FSIAD, the unmet medical need among women and the market opportunity for a pharmacologic treatment for FSAD and/or FSIAD.

Sabrina Martucci Johnson, President and CEO of Daré Bioscience, will host the webinar and will be joined by:

- Sheryl A. Kingsberg, PhD, Division Chief of Behavioral Medicine, Department of OBGYN, University Hospitals Cleveland Medical Center, Ohio, and Past President of ISSWSH, as well as NAMS, and
- James A. Simon. M.D., CCD, NCMP, IF, FACOG, Clinical Professor, Obstetrics and Gynecology, George Washington University and President and Medical Director of IntimMedicine Specialists®, as well as Past President of each of NAMS and ISSWSH.

A link to access the live webinar will be available under “Presentations, Events & Webcasts" in the Investors section of the Company's website at http://ir.darebioscience.com. Following the conclusion of the live event, a replay will be available under “Presentations, Events & Webcasts" in the Investors section of the Company's website at http://ir.darebioscience.com until September 1, 2023.

About Sildenafil Cream, 3.6%

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.

The previously announced positive topline data from the exploratory Phase 2b RESPOND study included findings that women treated with Sildenafil Cream had more satisfactory sexual events and experienced improvement in arousal lubrication and orgasm. As was the case with sexual desire, improvements in arousal lubrication and orgasm achieved maximum separation from placebo at the 8-week mark after randomization compared to baseline. These improvements in the Sildenafil Cream ITT group were maintained through the end of study assessment, demonstrating persistence while on treatment, whereas, in the placebo group, no such trends were observed, with no such improvements achieved at the 8-week mark. While a persistent response in arousal lubrication, orgasm and sexual desire was observed in the Sildenafil Cream ITT group through the end of study assessment, no endpoint achieved statistical significance at end of study. Daré intends to review the data with the FDA, including discussing the data from assessments as early as the 4- and 8-week mark after randomization where women randomized to Sildenafil Cream exhibited improvement.

About FSAD and FSIAD

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 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 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.

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.

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 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 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 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, Daré's plans for continued clinical development of Sildenafil Cream, the potential for Sildenafil Cream to be the first FDA-approved treatment for FSAD and/or FSIAD, 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, risk and uncertainties related to: the risk that topline results from a clinical trial, including the Phase 2b RESPOND study, are based on Daré's preliminary analysis of key efficacy and safety data and, following a comprehensive review of the study data, topline results may not accurately reflect the complete results from the study and the differences between topline results and complete results may be significant and may adversely impact the continued clinical development of the investigational product, including anticipated time and expense of continued development; the risk that data from the Phase 2b RESPOND study may not be predictive of positive results of any future clinical study, including in the event that a Phase 3 study of Sildenafil Cream is required to demonstrate statistically significant effect of the investigational product compared to placebo at time points beyond 8 weeks post-randomization; 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; 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 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 the COVID-19 pandemic, macroeconomic conditions and geopolitical events on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely commence, enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business to fulfill their contractual obligations to Daré; 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; cyber attacks, security breaches 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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