Daré Bioscience Announces Additional Positive Data from Phase 2b RESPOND Study of Sildenafil Cream, 3.6% in Women and Proposed Endpoints and Patient Population for Phase 3 Program

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Additional Analyses of Phase 2b Data Conducted in Population of Study Participants with Female Sexual Interest/Arousal Disorder (FSIAD), With Primary Complaint of Arousal Dysfunction

Achieved Statistical Significance and Clinically Meaningful Improvement in Phase 2b Co-Primary Endpoint Assessing Arousal Sensation, and Statistical Significance in Items from Phase 2b Co-Primary Endpoint Scale Evaluating Concern Related to Difficulties with Sexual Arousal in Subset Analyses

Data Support Advancing Co-Primary Endpoints and Selected Patient Population from Phase 2b to Proposed Phase 3 Program

Company is On Track for End of Phase 2 Meeting with FDA This Year

Sildenafil Cream Has Potential to Be First FDA-Approved Treatment for Any Form of Sexual Arousal Disorder in Women

SAN DIEGO, Nov. 01, 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 findings based on further analyses of data from the exploratory Phase 2b RESPOND study that evaluated Sildenafil Cream, 3.6% (Sildenafil Cream) in women with female sexual arousal disorder (FSAD).

The Phase 2b RESPOND study enrolled women with FSAD and included women who had sexual dysfunctions in addition to FSAD. Further analyses of Phase 2b RESPOND study data identified a subset of study participants—women with FSAD as well as women with FSIAD whose primary complaint was arousal dysfunction—that achieved statistically significant and clinically meaningful improvement in the Phase 2b co-primary endpoint of evaluating the efficacy of Sildenafil Cream versus placebo cream as measured by change from baseline to the end of the 12-week double-blind dosing period in the Arousal-Sensation Domain of the Sexual Function Questionnaire (p=0.04). In addition, only the Sildenafil Cream treatment group in this subset, and not the placebo group, demonstrated clinically meaningful improvement at the end of the 12-week period.

The other co-primary objective of the Phase 2b RESPOND study was to evaluate the efficacy of Sildenafil Cream compared to placebo cream as measured by the change from baseline to the end of the 12-week double-blind dosing period in the score for feeling concerned by difficulties with sexual arousal utilizing the Female Sexual Distress Scale – Desire, Arousal, Orgasm (FSDS-DAO). Analyses of the same subset of women in the Phase 2b RESPOND study (women with FSAD and women with FSIAD whose primary complaint was arousal dysfunction) demonstrated that the Sildenafil Cream treatment group achieved statistically significant improvement in several FSDS-DAO questions, including regarding guilt, stress, inadequacy, and embarrassment due to their sexual problems (p=0.02 to 0.05).

"After showing improvements in multiple aspects of the sexual experience, we believe that the further analyses of the Phase 2b RESPOND study data support advancing the Phase 2b co-primary endpoints to our Phase 3 program and evaluating the efficacy of Sildenafil Cream in a broader population of women—women with FSAD and FSIAD," saidSabrina Martucci Johnson, President and CEO of Daré Bioscience. "The further analyses bolster our belief that Sildenafil Cream has the potential to successfully address the significant unmet need of arousal disorder. We remain on track for an end of Phase 2 meeting to discuss these exciting findings with the FDA this year, and look forward to potentially initiating the first ever Phase 3 pivotal study for the treatment of arousal disorder in women. We also look forward to presenting these additional positive analyses at the upcoming meeting of the Sexual Medicine Society of North America in San Diego later this month."

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.

The Phase 2b RESPOND study was a first of its kind Phase 2b clinical study that included patient reported outcome (PRO) instruments to screen eligible women and a number of primary, secondary, and exploratory PRO assessments to measure

improvement in localized genital sensations of arousal and reduction in the distress that women experience with FSAD. There are no FDA-approved treatments for FSAD or FSIAD and thus there are no efficacy endpoints that have been previously validated in Phase 3 pivotal studies for potential treatments for FSAD or FSIAD. The Phase 3 study design for Sildenafil Cream, including primary and secondary efficacy endpoints and inclusion/exclusion criteria for study participants, will be determined following discussions with the U.S. Food and Drug Administration (FDA), including the company's end of Phase 2 meeting with the FDA.

About FSAD, FSIAD 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 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.

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.

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, Daré’s plans for continued clinical development of Sildenafil Cream, the potential primary endpoints and patient population to be evaluated in a Phase 3 clinical study, the timing of an end of Phase 2 meeting with the FDA related to 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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