Daré Bioscience Announces Interim Analysis of Phase 2b RESPOND Study of Sildenafil Cream, 3.6% in Women with Female Sexual Arousal Disorder

August 29, 2022

Study Enrollment Expected to Complete in 4Q-2022 with Approximately 150 Subjects

Topline Data of Phase 2b RESPOND Study Targeted for 2Q-2023

If clinical development is successful, Sildenafil Cream, 3.6% has the potential to be the first FDA-approved FSAD treatment option

SAN DIEGO, Aug. 29, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, and Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced that, based on the results of an interim analysis to evaluate the relative magnitude of the treatment effect, they expect to complete enrollment in the exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, 3.6% in 4Q-2022, allowing for a topline data announcement target of 2Q-2023. The interim analysis was conducted by an independent third-party statistical resource and both Daré and SST continue to remain blinded to results of the study by treatment group. The Phase 2b RESPOND clinical study is a multi-center, double-blind, placebo-controlled study to evaluate the efficacy and safety of Sildenafil Cream, 3.6% in premenopausal patients with female sexual arousal disorder (FSAD).

Sildenafil Cream is a proprietary topical formulation of sildenafil, a phosphodiesterase-5 (PDE-5) inhibitor, being developed as a first-in-category option for the treatment of FSAD. FSAD is the inability to reach or maintain a sufficient physical response to sexual stimulation and, of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction (ED) in men. Sildenafil is the active ingredient in a tablet for oral administration currently marketed under the brand name Viagra® for the treatment of ED in men.

"We are thrilled to have reached this important milestone for this study this year and look forward to evaluating the topline data next year," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Although numerous pharmaceutical products have been developed, tested and approved by the FDA to treat ED in men, there are no FDA-approved options for women with FSAD, an analogous condition. Completing this Phase 2b study will be a significant milestone in the development of what has the potential to be the first FDA-approved product to treat FSAD. Based on the relative treatment effect seen in the interim analysis we are comfortable with an enrollment target of 150 women completing the study, and believe these Phase 2b data will facilitate ongoing discussion and future alignment with the FDA regarding the pivotal registration program."

Unlike the oral formulations of PDE-5 inhibitors, Sildenafil Cream is designed to be applied locally to the vaginal tissue prior to sexual activity to facilitate vasodilation and increased blood flow directly to the genital tissue to improve the physical arousal response symptoms commonly associated with FSAD. Increasing blood flow to the genital tissue, as Sildenafil Cream is designed to do, has the potential to improve genital arousal response and overall sexual experience for women. This is similar to the way ED medications work in men by directing blood flow to the genitals when taken prior to sexual activity.

The Phase 2b RESPOND study evaluates Sildenafil Cream compared to a placebo cream in pre- and peri-menopausal women over the course of 12 weeks, in an at-home setting, following both a non-drug and placebo cream run-in period. The Phase 2b RESPOND study is a first of its kind Phase 2b study that includes patient reported outcome (PRO) instruments to screen eligible women with FSAD 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 and thus there are no efficacy endpoints that have been previously validated in Phase 3 pivotal studies for potential treatments for FSAD. The RESPOND study is designed to test the sensitivity of several efficacy endpoints and their ability to determine a treatment effect of Sildenafil Cream compared to placebo to inform the ongoing development program. The independent third-party statistical resource was provided with unblinded data in order to determine the relative magnitude of the treatment effect to enable a determination of next steps with study enrollment and enrollment targets.

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. For context on the potential market opportunity for an FDA-approved treatment for FSAD, 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 FSAD

FSAD is distinct from hypoactive sexual desire disorder (HSDD) in women, which is characterized primarily by a lack of sexual desire. FSAD 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. As with ED in men, FSAD is associated with insufficient blood flow to the genitalia.

About Sildenafil Cream, 3.6% and the Phase 2b RESPOND Study

Sildenafil Cream is an investigational proprietary cream formulation of sildenafil, a PDE-5 inhibitor, designed for topical administration to the vulva and vagina 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. Sildenafil Cream has been previously evaluated in Phase 1 and Phase 2a clinical studies. In a Phase 1 clinical study in 20 healthy post-menopausal women, topical sildenafil cream was safe and well tolerated at clinically relevant doses, and study subjects reported favorable product characteristics: easy to use and readily absorbed. In a Phase 2a study in women with FSAD (15 pre-menopausal and 16

post-menopausal), Sildenafil Cream increased measurable blood flow to the genital tissue compared to placebo cream. Further, data from a thermography study in six healthy women demonstrated significantly greater increases in genital temperature after administration of Sildenafil Cream compared to placebo cream, indicating a positive impact on genital blood flow during the 30-minute testing session, with statistical separation from placebo within the first 15 minutes of dosing.

Prior to commencement of the Phase 2b RESPOND clinical study of Sildenafil Cream, Daré completed a content validity study designed to identify and document the genital arousal symptoms that are the most important and relevant to women with FSAD. The findings of that non-interventional study helped facilitate alignment with the FDA on acceptable efficacy endpoints for the Phase 2b RESPOND study and future Phase 3 program, including a number of exploratory endpoints identified in the content validity study. The primary efficacy endpoint of the Phase 2b study is a composite endpoint that includes patient-reported improvement in genital sensations of arousal and reduction in distress associated with FSAD. While the Phase 2b RESPOND study was originally expected to randomize a minimum of 400 subjects into the double-blind dosing period from 40 to 50 sites in the U.S. to achieve 150 subjects per arm completing the 12-week double-blind dosing period, based on the analysis of unblinded data by the independent third-party statistical resource to evaluate the relative magnitude of the treatment effect, it was determined to complete enrollment in 4Q-2022 with a revised projected 150 subjects expected to complete the 12-week double-blind dosing period (approximately 75 subjects per arm). The reduction in the number of subjects should not be viewed as indicative of the magnitude of the treatment effect. The relative magnitude of the treatment effect seen in the interim analysis should not be viewed as predictive that topline data will show Sildenafil Cream achieved the efficacy endpoints of the Phase 2b study.

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, fertility, and vaginal and sexual health. 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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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 hormone therapy following menopause. 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 the timing of the completion of enrollment in the Phase 2b RESPOND clinical study and of the topline data announcement, the potential of Sildenafil Cream, 3.6% to be approved by the FDA, and the market potential of Sildenafil Cream, 3.6%, if approved by the FDA . 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 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; 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; 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 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 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 risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product and Daré's product candidates, if approved; 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, product candidates or business activities; 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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