Daré Bioscience Announces Availability of Publication on the Patient-Centered Concept Elicitation Study for Female Sexual Arousal Disorder in The Journal of Sexual Medicine

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The Concept Elicitation Study Informed the Selection of the Primary, Secondary, and Exploratory Endpoints Included in the Phase 2b RESPOND Clinical Study Evaluating the Efficacy and Safety of Sildenafil Cream, 3.6% in Premenopausal Patients with Female Sexual Arousal Disorder

Topline Data from the Exploratory Phase 2b RESPOND Study are Anticipated 2Q-2023

SAN DIEGO, May 31, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the publication of results of the patient-centered study designed to elucidate the commonly reported symptoms, including severity of symptoms, associated with female sexual arousal disorder (FSAD). The publication, "Symptoms and associated impact in pre-and postmenopausal women with sexual arousal disorder: a concept elicitation study," appears in *The Journal of Sexual Medicine*.

The concept elicitation study, also referred to as a content validity study, to explore the experience of condition-associated symptoms and the relative importance of FSAD symptoms, including their severity, bother, and impact, on participants' health-related quality of life in pre- and postmenopausal women with FSAD was completed prior to commencement of the exploratory Phase 2b RESPOND clinical study of Sildenafil Cream, topline data for which are anticipated during 2Q-2023. The non-interventional study was conducted to identify and document the genital arousal symptoms that are the most problematic and most important symptoms to treat for women with FSAD. The findings of this content validity study helped facilitate alignment with the FDA on acceptable efficacy endpoints for the exploratory Phase 2b RESPOND study and future Phase 3 program, including a number of exploratory endpoints informed by the findings of the content validity study.

The content validity study included in-depth, qualitative, semi-structured concept elicitation interviews with premenopausal (n=23) and postmenopausal (n=13) women who were clinically diagnosed with FSAD by a trained sexual medicine clinician. The qualitative data from the interviews revealed a substantial physical and emotional burden of FSAD. The symptoms and impacts of this condition underscore the need for FDA-approved treatment options for pre- and postmenopausal women with FSAD. Results from this study also suggest that the manifestation and experience of FSAD are similar in pre- and postmenopausal women and that the unmet need for an FSAD treatment in the postmenopausal population is just as great as that of the premenopausal population.

The abstract of the journal article is available online: https://pubmed.ncbi.nlm.nih.gov/36763961/

"This peer-reviewed article, published in *The Journal of Sexual Medicine*, is an important resource for all stakeholders interested in women's sexual health and interested in better understanding the patient experience that informed the exploratory endpoints included in the Phase 2b RESPOND study in advance of topline data availability," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The findings from this content validity study, which was completed before commencing the Phase 2b RESPOND study, furthered our understanding of FSAD, a condition analogous to erectile dysfunction in men and for which there are currently no FDA-approved treatment options. Market research suggests that approximately 10 million women in the United States alone are distressed from experiencing symptoms associated with FSAD, including lack of or low sexual arousal, and are actively seeking solutions to improve their condition. The patient-driven insights from the content validity study add to our evolving understanding of her complex journey with FSAD as the findings revealed a substantial physical and emotional burden associated with FSAD. The prevalence of FSAD and the symptoms and impacts of the condition underscore the need for FDA-approved treatment options."

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. FSAD is distinct from hypoactive sexual desire disorder (HSDD) in women, which is characterized primarily by a lack of sexual desire. 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.

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 of sildenafil specifically designed to increase blood flow to the genital tissue in women. If development is successful, Sildenafil Cream has the potential to be the first FDA-approved treatment for FSAD.

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 while avoiding systemic side effects observed with oral formulations of PDE-5 inhibitors.

Daré and its collaborator Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, previously announced that topline data for the Phase 2b RESPOND study is targeted for 2Q-2023. The exploratory Phase 2b RESPOND 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 FSAD. The Phase 2b RESPOND study is a first of its kind Phase 2b clinical 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 exploratory Phase 2b 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.

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. 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 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 the timing of announcement of topline data from the Phase 2b RESPOND study of Sildenafil Cream, the importance of the content validity study, Sildenafil Cream's potential as a safe and effective therapy for FSAD, Sildenafil Cream's potential to be the first FDA-approved treatment for FSAD, and the market potential of 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: 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 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 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:

Lee Roth

Burns McClellan

lroth@burnsmc.com

646.930.4406

OR

Media on behalf of Daré Bioscience, Inc.:

Jake Robison

Evoke Canale

jake.robison@evokegroup.com

619.849.5383

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