Daré Bioscience Announces Initiation of Subject Enrollment in a Phase 1 Thermography Study to Support Pharmacodynamic and Pharmacokinetic Characterization of Sildenafil Cream, 3.6%

April 20, 2023

Phase 1 Thermography Study Quantitative Data Expected to Complement Patient Reported Outcome Data Collected in the Exploratory Phase 2b RESPOND At-Home Study

Topline Data for the Exploratory Phase 2b RESPOND Study Anticipated in 2Q-2023

SAN DIEGO, April 20, 2023 (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 initiation of screening and enrollment for a Phase 1 clinical study using thermography to assess the pharmacodynamic and pharmacokinetic characterization of Sildenafil Cream, 3.6% (Sildenafil Cream), a late-stage product candidate being developed as a potential new treatment for female sexual arousal disorder (FSAD). The quantitative pharmacokinetic and pharmacodynamic temperature data captured in a clinic setting in the study are expected to complement the patient reported outcome data collected in the ongoing Phase 2b RESPOND study, where the women use Sildenafil Cream in their home setting.

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. Sildenafil Cream is an investigational proprietary topical cream formulation specifically designed to increase blood flow to the genital tissue in women. If successful, Sildenafil Cream has the potential to be the first FDA-approved treatment for FSAD.

"This Phase 1, single-dose, double-blind, placebo-controlled, 3-way crossover study will utilize thermography to assess the pharmacodynamics and pharmacokinetics Sildenafil Cream in comparison with versions of the cream without the active ingredient, sildenafil," said Andrea Thurman, MD, Medical Director for Daré Bioscience. "The findings from this study, specifically the pharmacodynamic and pharmacokinetic data, are an important part of our comprehensive clinical development and regulatory plan for Sildenafil Cream and will add to our existing clinical and nonclinical data package to support the ongoing development program."

During the thermography study, vulvar temperature, a surrogate for vulvar blood flow, will be recorded by thermography in a clinic setting. 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. 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 increase blood flow directly to the genital tissue to improve the physical arousal response to address the lack of those genital arousal sensations commonly associated with FSAD.

"We are excited to announce that enrollment is underway in this important supplemental thermography study," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "This study has the potential to provide additional quantitative data regarding the ability of our cream formulation of the active ingredient sildenafil to increase genital blood flow, as assessed by vulvar temperature. These data are expected to complement forthcoming clinical findings from our Phase 2b RESPOND trial in preparation for a Phase 3 program."

The Phase 1 thermography study of Sildenafil Cream is expected to enroll approximately 15 women and be completed in 2023.

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 anticipated timing of topline data from the Phase 2b RESPOND study of Sildenafil Cream, expectations regarding the Phase 1 thermography study of Sildenafil Cream, and the potential for Sildenafil Cream to be the first FDA-approved treatment for FSAD. 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 development of a product candidate requires more clinical or nonclinical studies than Daré anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; 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 loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions such as inflation, rising interest rates 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 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

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.