Daré Bioscience Announces Positive End-of-Phase 2 Meeting with FDA on Development of Sildenafil Cream, 3.6% in Female Sexual Arousal Disorder and Provides Company Focus Areas for 2024

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

SAN DIEGO, Jan. 31, 2024 (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 the successful completion of an end-of-Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration (FDA), supporting advancement of Sildenafil Cream, 3.6% (Sildenafil Cream) for the treatment of female sexual arousal disorder (FSAD) to a Phase 3 clinical study. The Company also provided an update on focus areas for 2024.

Progressing Towards Sildenafil Cream Phase 3 Pivotal Study

The Company and the FDA aligned on key elements of the Phase 3 program to support a New Drug Application (NDA) filing, including confirming that:

- FSAD is acceptable as an indication.
- The trials can be conducted in a premenopausal FSAD-only population.
- 12-weeks of blinded treatment to assess efficacy may be acceptable, provided that the trials are adequately powered for efficacy assessment. This is a shorter period of blinded treatment than the 24 weeks recommended in 2016 draft FDA guidance for developing drugs for the treatment of low sexual interest, desire and/or arousal in women.

Additionally, the FDA indicated that feedback is forthcoming on the following:

- Primary and secondary patient reported outcome endpoints which will be used in Phase 3 pivotal trials and support potential product registration and labeling.
- Additional information on data that may be needed in an NDA submission to appropriately qualify any ingredient (other than sildenafil) for the vaginal route of administration.

Daré has also requested clarification on the safety database (size and duration of exposure) required for an NDA submission.

"We are pleased to have had a positive EoP2 meeting with the FDA as we work towards aligning on the Phase 3 program for Sildenafil Cream, which has the potential to address the significant unmet need associated with arousal disorder, which impacts approximately 10 million women in the U.S.," said Dr. Andrew Goldstein, M.D., Medical Advisor for Daré Bioscience. "Given that there are currently no FDA-approved products for FSAD, we appreciate the FDA's guidance and support and look forward to finalizing the Phase 3 protocol as we work to advance this product candidate into its first Phase 3 clinical study."

The EoP2 meeting was supported by positive data from the exploratory Phase 2b RESPOND clinical study, which assessed arousal sensation and evaluated concerns related to difficulties with sexual arousal over a 12-week double-blinded treatment period. The Phase 2b study results identified the subgroup of patients most likely to benefit from therapy and achieve a meaningful improvement, and in those subjects demonstrated that Sildenafil Cream improved arousal sensation, desire, orgasm, as well as stress, guilt, and embarrassment about the sexual dysfunction. The Phase 2b data are being used to enrich the odds of a successful Phase 3 program. There are currently no FDA-approved therapies for the treatment of FSAD.

Building on 2023 Achievements, Looking at 2024

In addition to the significant progress with Sildenafil Cream, Daré continues to build on numerous milestones and achievements from 2023.

"Continued execution against our strategy throughout 2023 has positioned us well for 2024 as we accelerate our portfolio of novel investigational therapies, particularly those that have already demonstrated proof of concept and their potential to expand treatment options, improve outcomes, and enable convenience for women with some of the most persistent unmet needs," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We remain focused on advancing our key pipeline programs, including our ongoing pivotal Phase 3 clinical study for Ovaprene, and continuing efforts toward our goal of advancing Sildenafil Cream into Phase 3 this year. Each of these programs – if approved – represents a potential first-in-category opportunity, and one of the most potentially disruptive therapeutic candidates for women in decades."

About FSAD 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.

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, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); 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, Daré's plans for continued clinical development of Sildenafil Cream, including the details and anticipated timing of commencement of a Phase 3 study, the potential for Sildenafil Cream to be the first FDA-approved treatment of FSAD, Daré's program development focus for 2024, and the potential market opportunity for Sildenafil Cream, Ovaprene and Daré's other investigational products. 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; 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 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 data from clinical studies of its product candidates; 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 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 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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