Daré Bioscience Presents Positive Sildenafil Cream, 3.6% Data Supporting Further Development for the Treatment of Female Sexual Arousal Disorder

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SAN DIEGO, March 09, 2020 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in women's health innovation, today announced the presentation of positive findings from a previously reported investigational study that used thermography technology to assess the pharmacodynamics of Sildenafil Cream, 3.6% (Sildenafil Cream) in healthy women. The presentation was made at the International Society for the Study of Women's Sexual Health (ISSWSH) Annual Meeting 2020, which took place in Orlando, FL, March 5-8, 2020.

Female Sexual Arousal Disorder (FSAD), a condition characterized primarily by an inability to attain or maintain sufficient genital arousal during sexual activity, is analogous to erectile dysfunction (ED) in men, and 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. Daré Bioscience, in collaboration with Strategic Science & Technologies, LLC (SST), is developing Sildenafil Cream as a potential treatment for FSAD. Sildenafil Cream is a topically administered formulation of sildenafil, a PDE5 inhibitor, designed to increase local blood flow and provide a potential improvement in genital arousal utilizing the same pathway that is active in ED medications for men.

Market research suggests that 33% of women in the U.S., ages 21 to 60 years old, experience symptoms of low or no sexual arousal, and 16%, or approximately 10 million women, are distressed and are seeking a solution to improve their condition. To put the market opportunity for an FDA-approved FSAD treatment in context, the prevalence of complete ED is estimated to be about 5% of men at age 40, increasing to about 15% at age 70.

"While oral sildenafil is effective for men, it is not an optimized way to achieve the same response in women," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "With the potential to deliver sildenafil in a fast-acting cream that can be locally applied, we may be able to offer the benefits of increased blood flow and improvement in genital sexual arousal response without the systemic issues observed with the oral formulation."

During the thermography study, genital temperature, a surrogate for genital blood flow, was captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study, which was designed to evaluate up to 10 subjects, achieved the study objectives based on a planned interim analysis of the first 6 completed subjects. The assessments consisted of the screening visit (visit 1), the double-blind dosing of placebo or active Sildenafil Cream (visits 2-3) and a safety follow-up. The thermography study is part of a comprehensive clinical development and regulatory plan for Sildenafil Cream that Daré Bioscience intends to implement in collaboration with SST.

"The data from this study are very encouraging," said the principal investigator for the study, Dr. Irwin Goldstein, Director of Sexual Medicine at Alvarado Hospital and Director of San Diego Sexual Medicine. "We saw statistically significant increases in genital temperature, a surrogate for genital blood flow, and self-reported arousal response when compared to placebo."

Dr. Irwin Goldstein is a recognized leader in the treatment of both male and female sexual disorders and the 2009 recipient of the World Association for Sexual Health Gold Medal award in recognition of lifetime contributions to the field.

In December 2019, Daré announced alignment with the FDA on the design of an at-home Phase 2b clinical study of Sildenafil Cream that it plans to initiate in 2020, including the patient reported outcome (PRO) instruments to be used to screen eligible patients with FSAD and to measure achievement of the primary efficacy endpoints. The Phase 2b study is designed to evaluate Sildenafil Cream compared to placebo cream over 12 weeks of dosing following both a non-drug and placebo run-in period.

A copy of the presentation made at the ISSWSH Annual Meeting is available on the Events and Presentations page of Daré's investor relations website (http://ir.darebioscience.com).

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene ®, a hormone-free, monthly contraceptive intravaginal ring 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®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré's full portfolio of women's health product candidates, and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations 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 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

on its investor relations website (https://darebioscience.gcs-web.com/) 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 on the investor relations page of Daré's website mentioned above.

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," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the potential of Sildenafil Cream to successfully treat FSAD without the systemic issues observed with the oral formulation of sildenafil, the usefulness of the thermography study to clinical development and potential regulatory approval of Sildenafil Cream for FSAD, and the design and timing for initiation of the Phase 2b clinical study of Sildenafil Cream in FSAD patients. 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 and continue as a going concern; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to conduct and design 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; the risk that positive findings in early clinical studies of a product candidate may not be predictive of success in subsequent clinical studies of that candidate; the risk that a product candidate may fail to demonstrate equivalent or superior efficacy and/or safety in a pivotal clinical study compared to results from a pre-pivotal study or studies; Daré's ability to retain its licensed rights to develop and commercialize a 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 candidates; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; 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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