Daré Bioscience, Inc. Announces Positive Results in Thermography Feasibility Study with Sildenafil Cream, 3.6%, a Potential Therapy for Female Sexual Arousal Disorder

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SAN DIEGO, June 17, 2019 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in women's health innovation, today announced positive findings from an investigational study designed to evaluate the feasibility of using thermography technology to assess the pharmacodynamics of Sildenafil Cream, 3.6% (Sildenafil Cream) in normal healthy women.

Sildenafil is the active ingredient in a tablet for oral administration marketed under the brand name Viagra®, which is indicated for the treatment of erectile dysfunction (ED) in men. Daré Bioscience, in collaboration with Strategic Science & Technologies, LLC (SST), is developing Sildenafil Cream as a potential treatment for female sexual arousal disorder (FSAD), a condition analogous to ED in men. Sildenafil Cream is a topically administered formulation of sildenafil designed to increase local blood flow and provide a potential improvement in genital arousal response and overall sexual experience for women. This is similar to the way ED medications work in men by directing blood to the genitals when taken before sexual activity. There are no FDA-approved drugs for the treatment of FSAD. If the clinical development program is successful, Sildenafil Cream has the potential to be the first FDA-approved FSAD treatment option.

"The results from the first six subjects to complete all assessments indicate the utility of thermography technology to detect statistically meaningful differences in genital temperature changes, a surrogate for genital blood flow, and support the ongoing evaluation of Sildenafil Cream as a treatment for FSAD," said Dr. Tuuli Kukkonen, C.Psych., an Associate Professor in the Department of Family Relations and Applied Nutrition at the University of Guelph in Ontario, Canada and an established expert in thermography research. "Specifically, in this initial small sample of healthy women, the data demonstrate significantly greater increases in genital temperature after administration of Sildenafil Cream compared to both placebo cream as well as no cream at all, indicating a positive impact on genital blood flow during the 30 minute testing session," continued Dr. Kukkonen.

The principal investigator for the thermography study, Dr. Irwin Goldstein, Director of Sexual Medicine at Alvarado Hospital and Director of San Diego Sexual Medicine, 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. "We are encouraged by these findings as we believe these results further validate Sildenafil Cream as a potential treatment for FSAD as an on-demand solution to prepare the body for a more pleasurable sexual experience," said Dr. Goldstein.

"This study is part of our larger FSAD development program for Sildenafil Cream, and these findings give us greater insight into the physiologic activity and time-to-effect that we should expect to see in the larger studies currently planned for the program," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience.

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, and thus additional subjects will not be enrolled. 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 development plan includes an ongoing non-interventional study intended to support the validity of FSAD-specific patient reported outcome (PRO) measures to be utilized to assess efficacy of Sildenafil Cream in Phase 2 and Phase 3 clinical studies, as well as an at-home dosing study anticipated to commence before the end of 2019, which together constitute the Sildenafil Cream Phase 2b program.

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.

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 non-hormonal, monthly contraceptive intravaginal ring; 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 the company's website mentioned above.

This press release includes information obtained from, and makes reference to, trade and statistical services and other third-party publications and sources. Daré has not independently verified such information and, although the company is not aware of inaccuracies in such third-party information, there can be no assurance as to its accuracy.

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, 3.6% to be the first FDA-approved FSAD treatment option, the usefulness of the thermography study to clinical development and potential regulatory approval of Sildenafil Cream, 3.6% for FSAD, and the timing of initiation or completion of clinical studies of Sildenafil Cream, 3.6%. 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; 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 potential for results of a completed clinical study to be different from interim findings; 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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