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

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**Sildenafil Cream, 3.6% has the Potential to Receive the First FDA Approval for Female Sexual Arousal Disorder**

SAN DIEGO, Nov. 27, 2018 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in clinical-stage women's health innovation, today announced that it is currently enrolling patients in an investigational study designed to evaluate the feasibility of using thermography technology to assess the pharmacodynamics of Sildenafil Cream, 3.6% in normal healthy women. Sildenafil, the active ingredient in Sildenafil Cream, 3.6%, is marketed in an oral dosage form under the brand name Viagra® for the treatment of erectile dysfunction in men. Daré Bioscience, in partnership with Strategic Science & Technologies, LLC (SST), is developing Sildenafil Cream, 3.6% as a potential treatment for female sexual arousal disorder (FSAD). During the thermography study, genital temperature, a surrogate for genital blood flow, will be captured and recorded utilizing an infrared camera capable of detecting heat patterns from blood flow in body tissues. The study consists of the screening visit (visit 1), the double-blind dosing of placebo or active cream (visits 2-3) and a safety follow-up.

"We are excited to announce that enrollment is underway in this thermography study," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "This study is part of our larger FSAD development program, and reflects capital-efficient activities we are pursuing to enrich and enhance the Phase 2b program. This small exploratory study has the potential to provide greater insight into the physiologic activity and time to effect resulting from the application of Sildenafil Cream, 3.6% externally to the vulva and internally in the vagina, which would further inform and support the design of our Phase 2b at-home study, anticipated to commence in 2019."

Sildenafil Cream, 3.6% is a proprietary cream formulation specifically designed to increase blood flow to the genital tissue in women, leading to a potential improvement in genital arousal response during sexual activity. If successful, Sildenafil Cream, 3.6% has the potential to be the first FDA-approved FSAD treatment option.

"The thermography study is part of a comprehensive clinical development and regulatory strategy that includes an upcoming content validity study to support the implementation of FSAD specific patient reported outcome (PRO) instruments, as well as an at-home dosing study which together constitute our Phase 2b program," said Mary Jarosz, Global Head of Regulatory Affairs for Daré Bioscience.

The principal investigator for the thermography study is Dr. Irwin Goldstein, 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 pleased to be working with SST and Daré on the Sildenafil Cream, 3.6% program, leveraging the known therapeutic benefit of Viagra® to stimulate increased blood flow to the genital tissue," said Dr. Goldstein. "There are no approved drugs for the treatment of FSAD and Sildenafil Cream, 3.6% has the potential to be an on-demand solution to prepare the body for a more pleasurable sexual experience."

**About Sildenafil Cream, 3.6% and 3Q2018 Type C Meeting with the FDA**

Sildenafil Cream, 3.6% has the potential to be the first FDA-approved FSAD treatment option. Unlike other female sexual disorders, FSAD is characterized primarily by an inability to attain or maintain sufficient physical sexual arousal that causes distress or interpersonal difficulty. It is the closest analog in women to erectile dysfunction in men. While increased attention has been focused on female sexual dysfunction over the past several years, no pharmacologic options have yet been U.S. Food and Drug Administration (FDA) approved for FSAD. In a Phase 2a trial, Sildenafil Cream, 3.6% increased measurable blood flow to the vaginal tissue in both pre- and postmenopausal women with FSAD compared to placebo.

During the third quarter of 2018, we had a Type C meeting with the FDA regarding the Phase 2b program for Sildenafil Cream, 3.6%. The objective of this meeting was to align with the agency on key aspects of the Phase 2b and the overall clinical program to support the planned New Drug Application, or NDA, including the screening assessments used to accurately diagnose FSAD, the PRO instruments to be used as primary efficacy endpoints for pivotal clinical studies, study duration, and the target patient population to be studied.

Based on the outcome of this meeting, in the fourth quarter of 2018, we will commence Phase 2b related activities for Sildenafil

Cream, 3.6% with the initiation of a content validity PRO study to demonstrate that the FSAD symptoms we plan to assess in our Phase 2b and our pivotal studies are the most important and relevant to our target patient population and are also acceptable efficacy endpoints for the FDA. After the content validity PRO study is completed and before the Phase 2b at-home trial is initiated, we plan to request another Type C meeting to obtain the FDA's guidance on whether it agrees that the PRO instruments are content valid for the target population.

**About Daré Bioscience**

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's reproductive and sexual health. The company's mission is to identify, develop and bring to market a portfolio of novel, differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes two potential first-in-class candidates in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive vaginal ring, and Sildenafil Cream, 3.6%, a potential treatment for female sexual arousal disorder utilizing the same active ingredient as Viagra®. To learn more about Daré's full portfolio of women's health products, and mission to deliver novel 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 uses these channels to communicate with its investors and the public about the company and other company-related matters. The information Daré posts on its investor relations website 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.

**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, the timing of initiation or completion of the company's clinical studies, and the company's ability to advance its product candidates through clinical development and regulatory approval. 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: our ability to raise additional capital when and as needed; our ability to develop and commercialize our product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for our product candidates in a timely manner; our 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 efficacy of our product candidates; our ability to retain our licensed rights to develop and commercialize a product candidate; our ability to satisfy the monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the critical patents and related intellectual property related to our product candidates; developments by our competitors that make our product candidates less competitive or obsolete; our dependence on third parties to conduct clinical trials; our ability to adequately protect or enforce our, or our licensor's, intellectual property rights; the lack of patent protection for the active ingredients in certain of our product candidates which could expose our 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 our intellectual property rights. Our forward-looking statements are based upon our 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 our risks and uncertainties, you are encouraged to review our documents filed with the SEC including our 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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