Daré Bioscience, Inc. Announces Initiation of Content Validity Study for 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. 29, 2018 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in clinical-stage women's health innovation, and Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced the initiation of a content validity study intended to support the use of specific patient reported outcome (PRO) measures to assess efficacy in female sexual arousal disorder (FSAD) patients in the Phase 2b and Phase 3 program for Sildenafil Cream, 3.6%.

This non-interventional study is designed to explore the experience of FSAD and evaluate the relevance of the selected PRO measures based on patients' own experiences and determine patients' understanding of the items, instructions, and response options of the selected PRO measures. Subjects that meet the inclusion criteria will participate in one-on-one, in-depth interviews conducted by subject matter experts in the field of clinical outcome assessments and female sexual medicine, which include thought leaders in the field of sexual medicine that are a subset of the sites that are expected to enroll subjects into the Phase 2b at-home interventional study. This non-interventional content validity study provides a unique opportunity to pilot the methods intended to be used, subject to U.S. Food and Drug Administration (FDA) approval, to identify, screen and diagnose women with FSAD in the Phase 2b at-home interventional study.

"We're excited to announce that we have reached this milestone with the initiation of the content validity study for our Sildenafil Cream, 3.6% program," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Although numerous pharmaceutical products have been developed, tested and approved to treat erectile dysfunction (ED) in men, women continue to lack effective options for FSAD, an analogous condition. Sildenafil is marketed in an oral dosage form under the brand name Viagra® for the treatment of ED in men, and we plan to leverage the existing data and safety profile of the Viagra® brand for our Sildenafil Cream, 3.6% program. Correct selection and implementation of a validated PRO to assess efficacy is a critical component of our successful Phase 2b and Phase 3 program. The goal of the study is to demonstrate that women both understand the PRO items and agree that they capture their most important and relevant symptoms and impacts of FSAD. We believe that establishing a content valid and well-understood PRO tool will help us provide confidence in the efficacy endpoints selected for the Phase 2b study."

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 content validation study is part of a robust clinical development program designed to support this innovative application of sildenafil for the treatment of FSAD," said Steven Brugger, President and Chief Operating Officer of SST. "Working in concert with the FDA we look forward to advancing the program towards important near-term value inflection milestones in the Phase 2b program, beginning with the content validity study."

About FSAD

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 ED in men. While increased attention has been focused on female sexual dysfunction over the past several years, no pharmacologic options have yet been 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.

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 ability to demonstrate content validity of the proposed PRO instrument for Phase 2b and Phase 3 studies of Sildenafil Cream, 3.6% for FSAD, the ability to leverage existing safety and efficacy data of the Viagra® product for the Sildenafil Cream, 3.6% program, and the company's ability to advance its product candidates, including Sildenafil Cream, 3.6%, 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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