Daré Bioscience Announces Completion of its Content Validity Study to Support the Continued Clinical Development of Sildenafil Cream, 3.6%, a Potential Therapy for Female Sexual Arousal Disorder

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Sildenafil Cream, 3.6% has the Potential to Be the First FDA-Approved Product for FSAD

SAN DIEGO, Sept. 09, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, and Strategic Science & Technologies, LLC (SST), a Cambridge, MA based novel topical drug delivery company, today announced the completion of a content validity study, a non-interventional study integral to initiating the at-home, product dosing portion of the Sildenafil Cream, 3.6% (Sildenafil Cream) Phase 2b program. Daré plans to review the findings of the content validity study with the U.S. Food and Drug Administration (FDA) in a Type C meeting and to seek alignment on the patient reported outcome (PRO) instruments to be used to screen eligible patients with Female Sexual Arousal Disorder (FSAD) and to assess the efficacy of Sildenafil Cream in treating FSAD.

"Since there are no products yet approved by the FDA for the FSAD indication, we believe the data we collected are truly groundbreaking," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We look forward to meeting with the FDA later this year, and presenting the rigor that went into the study and the data collected. Our intent is to utilize our findings to formulate a PRO efficacy endpoint and screening strategy designed specifically for FSAD, with the goal of commencing our Phase 2b study before the end of 2019."

The content validity study was designed to demonstrate that women clinically diagnosed with FSAD can understand the items, instructions and response options of the proposed PRO instruments (specifically those questions focused on genital arousal) and to confirm that the content within the PRO instruments captures the most important and relevant symptoms of FSAD patients. Participants who met the eligibility criteria participated in one-on-one, in-depth interviews conducted by subject matter experts in the field of clinical outcome assessments and female sexual medicine. Pending alignment with the FDA, the data from this non-interventional study is intended to be used as the basis to identify and screen women with FSAD in the Phase 2b and Phase 3 studies, as well as to evaluate their response to the investigational product, Sildenafil Cream.

Of the various types of female sexual dysfunction disorders, FSAD is most analogous to erectile dysfunction (ED) in men and is characterized primarily by an inability to attain or maintain sufficient genital arousal during sexual activity that causes distress or interpersonal difficulty. Despite a number of approved prescription products for ED, no pharmacologic options have yet been approved by the FDA for FSAD. Sildenafil, the active ingredient in Sildenafil Cream, is marketed in an oral dosage form under the brand name Viagra® for the treatment of ED in men.

Sildenafil Cream is a proprietary cream formulation of sildenafil 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 in clinical studies, Sildenafil Cream has the potential to be the first FDA-approved pharmacologic treatment option for FSAD. In a Phase 2a trial, Sildenafil Cream increased measurable blood flow to the vaginal tissue in both pre- and post-menopausal women with FSAD compared to placebo cream. Further, data from a thermography study in healthy women demonstrated significantly greater increases in genital temperature after administration of Sildenafil Cream compared to after administration of placebo cream as well as no cream at all, indicating a positive impact on genital blood flow during the 30-minute testing session.

"The completion of the content validity study is a critical milestone toward advancing into the Phase 2b and Phase 3 stages of the development plan," said Steven Brugger, President and Chief Operating Officer of SST. "We are excited to be working at the cutting edge of research focused on women's sexual health and to advance a potential first-in-category treatment option for women suffering with FSAD."

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; 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 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: www.darebioscience.com.

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 treat FSAD, the potential of Sildenafil Cream to be the first FDA-approved product for FSAD, the usefulness of the content validity study to the clinical development and potential regulatory approval of Sildenafil Cream, and the timing of development milestones for Sildenafil Cream. 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; 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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