Daré Bioscience Announces Alignment with the FDA on Phase 2b Study Design and Novel Primary Endpoint PRO Instruments 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, Dec. 11, 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 outcome of a Type C meeting with the U.S. Food and Drug Administration (FDA) where alignment was reached on the patient reported outcome (PRO) instruments to be used in a Phase 2b clinical study of Sildenafil Cream, 3.6% (Sildenafil Cream) to screen eligible patients with Female Sexual Arousal Disorder (FSAD) and to assess the efficacy of Sildenafil Cream in treating FSAD. The discussions with the FDA followed the completion of a content validity study of the proposed PRO instruments, a non-interventional study integral to initiating the at-home, product dosing portion of the Sildenafil Cream Phase 2b program.

"We made excellent progress this year achieving alignment with the FDA on an appropriate and acceptable development plan for a drug to treat FSAD," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Importantly, we aligned with the FDA on the design of our Phase 2b study, including the PRO instruments to be used to measure achievement of the primary efficacy endpoints, namely improvement in localized genital sensations of arousal and reduction in the distress that women with FSAD experience. We are pleased that the FDA recognizes the validity of the PRO instruments to test the efficacy of a drug to treat FSAD that are specific to the Sildenafil Cream mechanism of action. This is a significant milestone in the development of what has the potential to be the first FDA-approved product to treat FSAD. In addition, we aligned with the FDA on several exploratory efficacy endpoints which will be measured in our Phase 2b study and could potentially prove to be additional measurements of efficacy in a future Phase 3 program. We are encouraged by the continued collaborative approach we are experiencing with all FDA divisions and are thrilled to have reached this point in the Sildenafil Cream development program."

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 several 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.

"We are very pleased to achieve this alignment with the FDA on the Phase 2b study design," 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."

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 and no cream at all, indicating a positive impact on genital blood flow during the 30-minute testing session.

As part of the Type C process, Daré and SST also confirmed with the FDA that no additional nonclinical or clinical data are required before initiating the Phase 2b at-home study. The companies also reviewed with the FDA what other data would be required to support a future New Drug Application (NDA) submission, including additional nonclinical and clinical studies that may need to be completed before NDA submission. Daré and SST will continue to actively engage with the FDA in 2020 to help ensure any required studies and activities are completed over the balance of the development program to support an NDA submission that will be complete for review.

The companies intend to initiate the Phase 2b at-home study in 2020. The Phase 2b is designed to evaluate Sildenafil Cream versus placebo over twelve weeks of dosing following both a non-drug and placebo run-in period.

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 vaginal contraceptive; 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 safely and effectively treat FSAD, the potential of Sildenafil Cream to be the first FDA-approved product for FSAD, the ability of the planned Phase 2b clinical study to demonstrate effectiveness of Sildenafil Cream in treating FSAD, the timing of development milestones for Sildenafil Cream, including initiation of the planned Phase 2b clinical study, active engagement with the FDA in 2020 regarding development of Sildenafil Cream, and the potential that an NDA for Sildenafil Cream submitted to the FDA will be accepted as complete for review. 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; 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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