Daré Bioscience Announces Initiation of Pivotal Phase 3 Study of DARE-BV1 in Patients with Bacterial Vaginosis

June 17, 2020

Topline data readout anticipated by the end of 2020

SAN DIEGO, June 17, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the initiation of the *DARE-BVFREE* study, a multi-center, double-blind, placebo-controlled Phase 3 clinical study of DARE-BV1 for the treatment of bacterial vaginosis.

DARE-BV1 is an investigational thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% being evaluated as a one-time, vaginally-administered treatment for bacterial vaginosis. The DARE-BVFREE study is expected to enroll approximately 240 participants, ages 12 and older, diagnosed with bacterial vaginosis across multiple clinical sites in the United States. The primary endpoint is clinical cure of bacterial vaginosis, defined as resolution of specified clinical signs and symptoms, at the test-of-cure visit to occur 21 to 30 days after enrollment in the study. The total study duration will be approximately one month for each individual participant.

"The initiation of the DARE-BVFREE study is a critical milestone for Daré as we advance our portfolio of novel women's health programs to meaningful value inflection points," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We worked closely with our study investigators to achieve commencement of this pivotal study on our previously communicated timeline, despite disruptions related to the COVID-19 pandemic, and we continue to anticipate reporting topline data in 2020. If this single Phase 3 study is successful, we intend to file a new drug application with the FDA for DARE-BV1 in 2021."

DARE-BV1 has received both Fast Track and Qualified Infectious Disease Product designations from the FDA for the treatment of bacterial vaginosis. Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Fast Track designation for DARE-BV1 underscores that bacterial vaginosis is a serious infection for which current treatment options are inadequate.

"DARE-BV1 demonstrated an 86% clinical cure rate in evaluable subjects at the test-of-cure visit that occurred 7 to 14 days after a single administration in an investigator-initiated proof of concept study," said David Friend, PhD, Chief Scientific Officer for Daré Bioscience. "If DARE-BV1 delivers a similarly high clinical cure rate in the Phase 3 pivotal study, we believe DARE-BV1 could become a new front-line treatment option for women diagnosed with bacterial vaginosis."

Bacterial vaginosis is estimated to effect more than 21 million women in the United States,[1] and with clinical cure rates ranging from 37 to 68%, currently available FDA-approved treatment options are insufficient for many women. Less than optimal clinical cure rates may also be a key driver of the high rate of recurrence of bacterial vaginosis. It is estimated that as many as 50% of women treated for bacterial vaginosis will experience a recurrence within 12 months of their treatment.[2]

The DARE-BVFREE study is a multicenter, randomized, double-blind, placebo-controlled study of DARE-BV1 (clindamycin phosphate vaginal gel, 2%) compared to placebo vaginal gel for the treatment of bacterial vaginosis. Patients will be evaluated at three time points: a Day 1 Screening/Randomization visit, a Day 7-14 Interim Assessment visit, and a Day 21-30 Test of Cure visit.

Trial design details can be found at ClinicalTrials.gov, study ID: NCT04370548, or https://clinicaltrials.gov/ct2/show/NCT04370548.

1. Centers for Disease Control and Prevention, Bacterial Vaginosis (BV) Statistics, viewed at https://www.cdc.gov/std/bv/stats.htm
2. The Journal of Infectious Diseases 2006; 193:1478–86; https://www.ncbi.nlm.nih.gov/pubmed/16652274

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 whose U.S. commercial rights are under a license agreement with Bayer; 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, the potential of a single administration of DARE-BV1 to safely and effectively treat bacterial vaginosis (BV), the potential for DARE-BV1 to demonstrate a higher clinical cure rate than current FDA-approved BV treatments and become a front-line treatment option for BV, the timing of availability of topline results of the DARE-BVFREE study, the potential for regulatory approval of DARE-BV1 based on a single, successful Phase 3 clinical study, namely the DARE-BVFREE study, and the significance of Fast Track designation for the DARE-BV1 program. 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; the effects of the COVID-19 pandemic on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré; 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 U.S. Food and Drug Administration (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 risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; 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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