Daré Bioscience Announces Publication of DARE-BV1 Proof of Concept Study for the Treatment of Bacterial Vaginosis

August 20, 2020

DARE-BV1 is an investigational, proprietary thermosetting hydrogel formulation of clindamycin phosphate 2% for one-time vaginal administration in patients diagnosed with bacterial vaginosis

SAN DIEGO, Aug. 20, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the publication of a proof of concept study of DARE-BV1 in *Clinical and Experimental Obstetrics & Gynecology*, an international journal focused on publication of high quality scientific research related to obstetrics and gynecology and women's health. DARE-BV1 is a novel thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% that is being evaluated as a one-time vaginally administered treatment for bacterial vaginosis (BV).

The publication, entitled "Proof of concept study of a novel bioadhesive clindamycin phosphate 2% vaginal gel to treat bacterial vaginosis," reported that a single dose of the study drug, now known as DARE-BV1, administered to 30 patients diagnosed with bacterial vaginosis showed a meaningful clinical cure rate of 86% in evaluable patients at the test-of cure visit. Clinical cure was defined as the resolution of specified clinical signs and symptoms of bacterial vaginosis that were present at the time of enrollment in the study.

"This proof of concept study suggests that DARE-BV1 has the potential to be a highly effective treatment option for bacterial vaginosis, the most common cause of vaginal symptoms among women," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "At the test-of-cure visit 7 to 14 days after dosing, 86% of the evaluable patients in the study were clinically cured of their bacterial vaginosis and 96% of those women remained clinically cured at the follow-up visit 21 to 30 days after dosing. There were no reports of adverse reactions to DARE-BV1 over the duration of the study."

Bacterial vaginosis is the leading cause of vaginitis worldwide and is estimated to affect more than 21 million women in the United States.[1,2] It is estimated that bacterial vaginosis is present in at least 15% of the sexually active population[3] and is associated with a variety of serious health issues including preterm birth, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV), and other chronic health problems.[2,4]

"Current FDA-approved treatments for the treatment of bacterial vaginosis offer clinical cure rates ranging from 37 to 68%," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience. "Alarmingly, as many as 50% of women treated for bacterial vaginosis will experience a recurrence within 12 months of treatment, which underscores the need for more effective treatment options for women." [5]

Daré recently announced the initiation of the DARE-BVFREE study, a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical study of DARE-BV1 for the treatment of 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.

"If DARE-BV1 delivers a similarly high clinical cure rate in the Phase 3 pivotal study as it did in the pilot study, we believe DARE-BV1 could become a new front-line treatment option for women diagnosed with bacterial vaginosis," said Ms. Johnson. "Given the anticipated short duration of the Phase 3 study, we expect to report topline data from the study by year-end 2020. Positive results from this single pivotal study will enable us to submit a new drug application for DARE-BV1 with the FDA in early 2021, two years from licensing the technology."

Earlier this year, Daré announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for DARE-BV1 for the treatment of bacterial vaginosis, in addition to receiving Qualified Infectious Disease Product (QIDP) designation for the treatment of bacterial vaginosis in August of 2019.

Fast Track designation is granted by the FDA for drugs that are intended for the treatment of serious or life-threatening disease or conditions, which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for more frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support approval. The Fast Track program is intended to facilitate development and expedite review of a Fast Track drug so that an approved product can reach the market expeditiously.

QIDP designation is available under Title VIII of the Food and Drug Administration Safety and Innovation Act, titled Generating Antibiotic Incentives Now (GAIN), which creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The primary incentive is a five-year exclusivity extension added to any exclusivity for which a QIDP qualifies upon FDA approval.

The publication entitled "Proof of concept study of a novel bioadhesive clindamycin phosphate 2% vaginal gel to treat bacterial vaginosis" is currently available in the Latest Articles section on the journal's website, or at https://ceog.imrpress.com/EN/10.31083/j.ceog.2020.04.5304.

1. Clinical Infectious Diseases 2007; 44:213–9; https://doi.org/10.1086/509577
2. Centers for Disease Control and Prevention, Bacterial Vaginosis (BV) Statistics, viewed at https://www.cdc.gov/std/bv/stats.htm
3. Clinical Infectious Diseases 2007; 44:220–1;https://doi.org/10.1086/509584

4. Onderdonk, A. et al. “The Human Microbiome during Bacterial Vaginosis,” Clinical Microbiology Reviews, April 2016 Volume 29 Number 2
5. 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 clinical-stage 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, the potential for DARE-BV1 to demonstrate a higher clinical cure rate than current FDA-approved drug products and become a front-line treatment option for bacterial vaginosis, the timing of availability of topline results of the DARE-BVFREE study and submission of a new drug application for DARE-BV1, 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 and QIDP designations 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 Daré’s ability to timely enroll, conduct and report results of its clinical trials and 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.

Contact:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth
Burns McClellan
lroth@burnsmc.com
212-213-0006

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.