Daré Bioscience Receives FDA Fast Track Designation for DARE-BV1 for the Treatment of Bacterial Vaginosis

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DARE-BV1 demonstrated an 86% clinical cure rate in evaluable subjects at the test-of-cure visit after a single administration in an investigator-initiated proof of concept study, which is higher than the clinical cure rates of current FDA-approved products

SAN DIEGO, March 10, 2020 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in women's health innovation, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for DARE-BV1 for the treatment of bacterial vaginosis (BV) in women. DARE-BV1 was previously granted Qualified Infectious Disease Product (QIDP) designation for the treatment of BV in August 2019. DARE-BV1 is a novel thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% being developed for one-time vaginal administration for the treatment of BV.

"BV is estimated to affect more than 20 million women in the United States and has been associated with pre-term birth and infertility. With clinical cure rates of current FDA-approved products in the range of 37-68% and a high rate of recurrence, this condition requires more innovative, effective medicines," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Our Fast Track Designation for DARE-BV1 underscores that BV is a serious infection for which current treatment options are inadequate and validates DARE-BV1's potential to address this unmet medical need."

BV is the most common cause of vaginitis worldwide.[1] While there are a number of FDA-approved treatment options for women diagnosed with BV, most have relatively low clinical cure rates (37-68%), which may be one of the key drivers of recurrence rates. It is estimated that as many as 50% of women treated for BV will experience a recurrence within twelve months of their treatment.[2] 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.

Daré plans to initiate a Phase 3 clinical study of DARE-BV1 in approximately 220 women with an anticipated topline data readout by the end of 2020 to support the New Drug Application (NDA) submission. Based on discussions with the FDA, the Phase 3 study will include a placebo control and assess the primary endpoint of clinical cure of BV (defined as resolution of specified clinical signs and symptoms from baseline visit) at the test-of-cure visit to occur 21 to 30 days after enrollment in the study. If this single Phase 3 study and the nonclinical studies to be conducted in parallel with the Phase 3 study are successful, Daré intends to file the NDA following the completion of the Phase 3 study.

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 frequent interactions with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed. 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.

BV has been associated with serious health issues, including preterm births, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.[3] It is estimated that BV is present in at least 15% of the sexually active population making it more common than urinary tract infections and many times more common than the Trichomonas vaginalis infection and vulvovaginal candidiasis.[4]

1. *Clinical Infectious Diseases* 2007; 44:213–9; https://doi.org/10.1086/509577
2. *The Journal of Infectious Diseases* 2006; 193:1478–86; https://www.ncbi.nlm.nih.gov/pubmed/16652274
3. *Centers for Disease Control and Prevention, www.cdc.gov/std/bv/stats.htm;* Onderdonk, A. et al. "The Human Microbiome during Bacterial Vaginosis," *Clinical Microbiology Reviews*, April 2016 Volume 29 Number 2
4. *Clinical Infectious Diseases* 2007; 44:220–1; https://doi.org/10.1086/509584

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 BV, the potential for DARE-BV1 to demonstrate a higher clinical cure rate than current FDA-approved BV treatments, the timing of the Phase 3 clinical study of DARE-BV1 and availability of topline results of the study, the potential for regulatory approval of DARE-BV1 based on a single, successful Phase 3 clinical study and the anticipated benefits of Fast Track designation for DARE-BV1. 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; the risk that positive findings in early clinical studies of a product candidate may not be predictive of success in subsequent clinical studies of that candidate; the risk that a product candidate may fail to demonstrate equivalent or superior efficacy and/or safety in a pivotal clinical study compared to results from a pre-pivotal study or studies; 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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