Daré Bioscience Receives QIDP Designation from the FDA for DARE-BV1 for the Treatment of Bacterial Vaginosis

August 12, 2019

DARE-BV1 Phase 3 registrational trial initiation expected in 4th quarter 2019

SAN DIEGO, Aug. 12, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that DARE-BV1, a novel thermosetting hydrogel containing clindamycin phosphate 2%, has been granted Qualified Infectious Disease Product (QIDP) designation by the U.S. Food and Drug Administration (FDA) for the treatment of bacterial vaginosis (BV) in women.

"Receiving QIDP designation for DARE-BV1 for the treatment of BV is validation that BV is a serious infection for which current treatment options are inadequate. Our novel thermosetting hydrogel technology delivering clindamycin has the potential to become a powerful new treatment option for health care providers struggling to adequately address and resolve this persistent vaginal infection," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "With clinical cure rates of currently approved products in the range of 37-68% and prevalence of BV in the U.S. estimated to be over 21 million among women ages 14–49, there is significant need for a more effective treatment. We believe the unique thermosetting hydrogel formulation characteristics of DARE-BV1 may result in better antibiotic delivery to the vaginal infection, which can lead to better clinical outcomes."

In an investigator-initiated proof-of-concept study, DARE-BV1 demonstrated an 86% clinical cure rate in the evaluable subjects at the test-of-cure visit (Day 7-14) after a single administration. Daré intends to commence a Phase 3 clinical study of DARE-BV1 in approximately 250 women in the fourth quarter of 2019. Based on prior discussions with the FDA, Daré believes that the Phase 3 study, if successful, would be sufficient for approval of DARE-BV1 to treat BV.

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. Additionally, DARE-BV1's QIDP designation makes it eligible for Fast Track designation and Priority Review.

About Bacterial Vaginosis (BV)

BV is the most common vaginal infection in women ages 15-44.[1] BV is characterized by a shift in the vaginal flora from the dominant Lactobacillus to a polymicrobial flora.[3] BV has been associated with serious health issues, including preterm births, infertility, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.[1,2]

1. Center for Disease Control and Prevention (CDC). www.cdc.gov/std/bv/stats.htm

2. Onderdonk, A. et al. "The Human Microbiome during Bacterial Vaginosis," Clinical Microbiology Reviews, April 2016 Volume 29 Number 2

About DARE-BV1

DARE-BV1 is a viscous liquid designed to undergo solution to gel (sol-to-gel) transition using body temperature as the trigger. This property allows the product to be more easily directed to the site of infection. Pre-clinical studies demonstrated that, by the process of "reverse thermal gelation," the viscosity of the base matrix increases up to four-fold upon reaching normal body temperature when compared to its viscosity at room temperature.

DARE-BV1 is formulated with clindamycin phosphate, a potent antibiotic, which has been found to be effective against organisms usually associated with BV such as Bacteroids spp., Peptococcus spp., Gardnerella vaginalis, Mobiluncus spp. and Mycoplasma hominis. Clindamycin, based on the PK-PD approach to dosing, can be classified as a time-dependent antibiotic for which maximizing the exposure time and the amount of drug is recommended. Topical application, safety, and efficacy of vaginally delivered clindamycin phosphate have been widely demonstrated in published literature. Daré plans to leverage the existing data and established safety profile of other products formulated with clindamycin phosphate to utilize the FDA's 505(b)(2) pathway for approval of DARE-BV1 as a treatment for BV in the U.S.

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 non-hormonal, 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 bioidentical 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 DARE-BV1 to treat bacterial vaginosis, the timing of Daré's Phase 3 clinical study of DARE-BV1, the potential for regulatory approval of DARE-BV1 based on a single, successful Phase 3 clinical study and the availability of the FDA's 505(b)(2) pathway for approval of 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; 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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