Daré Announces Presentation of Positive Clinical Findings for Vaginal Administration of Novel Formulation of Clindamycin Phosphate for the Treatment of Bacterial Vaginosis at the 2019 Annual Meeting of the Infectious Diseases Society for Obstetrics and Gynecology

August 8, 2019

DARE-BV1 is a proprietary formulation of clindamycin phosphate 2% for vaginal administration as a potential new first-line treatment for bacterial vaginosis

SAN DIEGO, Aug. 08, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the presentation of a poster at the upcoming annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology taking place August 8-10, 2019 in Big Sky, Montana. The poster presentation will highlight the results of an investigator-initiated, proof of concept study of DARE-BV1, a novel thermosetting bioadhesive vaginal gel technology containing clindamycin phosphate 2% for the treatment of bacterial vaginosis (BV).

"In the study, DARE-BV1 achieved a clinical cure rate of 86% at the test-of-cure endpoint, well above currently Food and Drug Administration approved treatments for BV, with clinical cure rates that range from 37-68%," said Dr. David Friend, Daré's Chief Scientific Officer. "We're excited to share these findings with the scientific and medical community as we believe that DARE-BV1 has the potential to be an important new option for the estimated 21 million women in the U.S. affected with 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.[2] 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]

DARE-BV1 features a novel thermosetting hydrogel delivery technology that is easy to apply, highly viscous and may have better bio-adhesion when compared to commonly prescribed creams and gels used to treat BV. It is believed that these unique formulation characteristics result in better antibiotic delivery to the vaginal infection leading to higher clinical cure rates and better clinical outcomes. Daré intends to start a single Phase 3 registrational trial of DARE-BV1 later this year.

The poster will be presented by Dr. Friend.

Presentation details are below. The poster will also be made available on the Events and Presentations page of Daré's investor relations website (http://ir.darebioscience.com).

Title:
Proof of Concept Study to Evaluate the Efficacy of a Novel Thermosetting Bioadhesive 2% Clindamycin Phosphate Vaginal Gel in the Treatment Bacterial Vaginosis

Dates & Times:
Thursday, August 8, 2019, 4:00 PM – 5:00 PM (Mountain Daylight Time)
Friday, August 9, 1:30 PM – 2:30 PM (MDT)

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 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 and the potential for regulatory approval of DARE-BV1 based on a single, successful Phase 3 clinical study. 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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