Daré Bioscience Announces the Presentation of DARE-BVFREE Phase 3 Clinical Trial Results at the 2021 Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists

April 26, 2021

SAN DIEGO, April 26, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that data from the DARE-BVFREE Phase 3 study of DARE-BV1, a thermosetting vaginal gel for the treatment of bacterial vaginosis, will be presented at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting. The meeting will be conducted virtually from April 30 - May 2, 2021.

The poster presentation will highlight the positive topline results from the DARE-BVFREE Phase 3 randomized, double-blinded, placebo-controlled clinical trial evaluating Daré's product candidate DARE-BV1 in women diagnosed with bacterial vaginosis, a condition that can cause serious health risks and very disruptive symptoms and is estimated to affect approximately 21 million women in the United States. DARE-BV1 is an investigational thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% designed as a one-time vaginally-administered treatment for bacterial vaginosis. The results from the DARE-BVFREE study demonstrate DARE-BV1's potential to provide improved clinical cure rates as compared to those of the current branded vaginal and oral prescription products for bacterial vaginosis.

DARE-BVFREE randomized 307 women diagnosed with bacterial vaginosis at 32 centers across the United States in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 or a single vaginal dose of placebo gel to be applied intravaginally within one day of randomization. Patients were evaluated during three clinic visits: Day 1 (screening and randomization visit), Day 7-14 (assessment visit), and Day 21-30 (test-of-cure visit). The study met its primary endpoint, demonstrating that as a primary therapeutic intervention a single vaginal dose of DARE-BV1 was statistically superior to placebo at Day 21-30 in the modified intent-to-treat (mITT) population (70% compared to 36% of subjects clinically cured). Additionally, DARE-BV1 demonstrated clinical cure rates of 77% at Day 21-30 and 81% at Day 7-14 in the per protocol population, compared to 43% and 30% for placebo cream, respectively. DARE-BV1 was well-tolerated in the study, and there were no early discontinuations due to adverse events.

"As a practicing physician focused on women's sexual and vaginal health, I welcome new treatment options for women suffering with bacterial vaginosis, a condition that has serious and deleterious consequences if not adequately addressed," said Andrew T. Goldstein, MD, FACOG, Medical Advisor of Daré Bioscience. "In the DARE-BVFREE trial, DARE-BV1 was well-tolerated and demonstrated clinical cure efficacy rates superior to those shown by current branded prescription products for treatment of bacterial vaginosis. The DARE-BVFREE trial followed the stringent enrollment criteria of the new 2019 FDA guidance document for developing drugs to treat bacterial vaginosis, and featured a patient population that we believe is very representative, including a large proportion of women, about 75%, who reported one or more episodes of bacterial vaginosis in the 12 months before they were randomized into the study."

In DARE-BVFREE, clinical cure was defined as resolution of the specific clinical signs that comprise the Amsel criteria; specifically, resolution of abnormal vaginal discharge associated with bacterial vaginosis, clue cells less than 20% of total epithelial cells on microscopy, and a negative 10% KOH "whiff" test. DARE-BV1 demonstrated clinical cure rates of 70% at Day 21-30 (primary endpoint) and 76% at Day 7-14 in the mITT population, compared to 36% and 24% for placebo cream, respectively, and rates of 77% at Day 21-30 and 81% at Day 7-14 in the per protocol population, compared to 43% and 30% for placebo cream, respectively. Consistent with the 2019 FDA guidance document, the mITT study population (N=180) excludes subjects from the intent-to-treat (ITT) population (N=307) who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline, or who have a baseline Nugent score of less than 7 (a score of 7 or greater represents bacterial vaginosis). The per protocol population (N=148) means subjects from the mITT population who have no major protocol violations that impact the primary or secondary endpoints or who received any other bacterial vaginosis therapy for any reason.

"Studies have shown recurrence rates of up to 60% within 12 months of treatment for bacterial vaginosis, and currently marketed FDA-approved products for the treatment of bacterial vaginosis have clinical cure rates in the mid-30% to the high-60% range," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "Based on the topline results of the DARE-BVFREE study, DARE-BV1 delivered clinical cure rate values greater than those of currently marketed FDA-approved products. If approved, we believe DARE-BV1 will be an important new and convenient one-time vaginally-administered treatment option with the potential to improve clinical outcomes and overall quality of life for women suffering with bacterial vaginosis."

The ePoster entitled *Phase 3 Study of a Single-Dose Bioadhesive Clindamycin 2% Gel for Bacterial Vaginosis*, authored by Steven Chavoustie, MD, Andrew Goldstein, MD, Judy Gendreau, MD, Christine Mauck, MD, MPH, David Friend, PhD, and Sharon Hillier, PhD, will be presented virtually by Steven Chavoustie, MD and will be available to meeting attendees on the ACOG website at https://www.acog.org, beginning April 30, 2021.

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 novel, investigational hormone-free monthly intravaginal contraceptive 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 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 the Investors section of its 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 in the Investors section of its website 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. In this press release, forward-looking statements include, but are not limited to, statements regarding DARE-BV1's clinical cure potential for bacterial vaginosis, DARE-BV1's potential importance to and utilization by women with bacterial vaginosis, if approved, and DARE-BV1's commercial potential. 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: the risk that topline results from a clinical trial, including the DARE-BVFREE study, are based on preliminary analysis of key efficacy and safety data and, following a comprehensive review of study data, such results may change and topline results may not accurately reflect the complete results from the clinical trial; the risk that the FDA, other regulatory authorities or members of the scientific or medical communities may not accept or agree with Daré's interpretation of or conclusions regarding the study data; 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 FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to design and conduct 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; the risk that developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; 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; cyber attacks, security breaches or similar events that compromise Daré's technology systems or those of third parties on which it relies and/or significantly disrupt Daré's business; 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.:
Tom Masterson
Allele Capital Partners
tmasterson@allelecapital.com
646.573.3216

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.