Daré Bioscience Announces FDA Acceptance and Priority Review of New Drug Application for DARE-BV1 for the Treatment of Bacterial Vaginosis

August 9, 2021

- *Six-month priority review granted for DARE-BV1 with PDUFA target action date set for December 7, 2021.*
- *NDA supported by positive data from the DARE-BVFREE Phase 3 study, which demonstrated clinical cure rates of 70-81% from a single vaginal dose of DARE-BV1.*
- *Ongoing strategic discussions underway to support a robust market introduction of the product in 2022, if approved.*

SAN DIEGO, Aug. 09, 2021 (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) accepted for filing the company's New Drug Application (NDA) for DARE-BV1 for the treatment of bacterial vaginosis. The FDA granted this application Priority Review and set a Prescription Drug User Fee Act (PDUFA) date of December 7, 2021 for the target completion of its review of the NDA. The FDA grants Priority Review to applications for potential drugs that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment of a serious condition.

The NDA is supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating 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 acceptance of this NDA marks a major milestone not only for Daré as a company but importantly for the 21 million women impacted by bacterial vaginosis," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "It is our goal to bring to market a product that has the potential to improve outcomes and convenience for women, as DARE-BV1 demonstrated it has the potential to do in the Phase 3 study, where a single vaginal dose of DARE-BV1 achieved clinical cure rates of 70-81%."

The results from the DARE-BVFREE study demonstrated DARE-BV1's potential to provide improved clinical cure rates in a convenient, one-time dose compared to those of currently branded FDA-approved products indicated for the treatment of bacterial vaginosis. Patients in the study 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 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. Current FDA-approved products have clinical cure rates in the range of only 37-68%.

DARE-BV1 has received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis. Under QIDP designation, if approved, DARE-BV1 will receive five years of additional market exclusivity on top of the three years available for having generated new clinical data.

Ongoing strategic discussions and other activities intended to support a robust market introduction of DARE-BV1 in 2022, if approved, are underway in parallel with the regulatory process. The FDA's target date for the completion of its review of December 7, 2021 aligns with Daré's intent to finalize and announce the commercialization strategy for DARE-BV1 in the U.S. in 2021. Commercialization arrangements for DARE-BV1 may include granting pharmaceutical companies with other commercial products in women's health an out-license to exclusively market, sell and distribute the product, if approved, in specific geographies; engaging commercial sales organizations to utilize their internal sales organizations and other commercial functions for market access, marketing, distribution, and other related services; or assembling a hybrid of these potential options to co-promote the product.

Information about the results from the DARE-BVFREE Phase 3 clinical study of DARE-BV1 currently can be found in the company's most recent investor presentation under "Presentations, Events & Webcasts" in the Investors section of the company's website at http://ir.darebioscience.com.

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, hormone-free, monthly contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a proprietary 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 to provide more effective treatment for bacterial vaginosis as compared to currently branded FDA-approved products for the treatment of bacterial vaginosis, DARE-BV1's commercial potential, Daré's ability to finalize and announce a commercialization strategy for DARE-BV1 in the U.S. in 2021, and the potential for a robust market introduction of DARE-BV1 in 2022. 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 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 data from the DARE-BVFREE clinical study and/or may require additional clinical or nonclinical studies of DARE-BV1 prior to approving the NDA; whether and when the NDA for DARE-BV1 pending with the FDA may be approved, which will depend on a variety of factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether DARE-BV1 will be commercially successful; decisions by the FDA impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of DARE-BV1; Daré's failure to timely establish or leverage third-party partnerships or collaborations to commercialize its product candidates, if approved; 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 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; 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.

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