Daré Bioscience Announces Grant to Develop Novel Hydrogel Formulation for Delivery of Live Biotherapeutics to Support Vaginal Health

November 15, 2022

Grant Funds Will Support Development of a Reconstitutable Vaginal Thermosetting Gel Formulation to Ultimately Serve as a Delivery Vehicle that Allows Administration of Live Biotherapeutics at the Point of Care in a Wide Range of Settings

SAN DIEGO, Nov. 15, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced it has received a grant from the Bill & Melinda Gates Foundation (the foundation) of $584,986 to support activities related to development of a vaginal thermosetting gel formulation for the delivery of live biotherapeutics that can be reconstituted at the point of care. If successful, the formulation could be carried forward for further development as a delivery vehicle with potential to enhance the availability of novel therapeutics for vaginal health in the United States and worldwide, including in countries with varying climatic conditions and/or where extended storage may be required.

Vaginal health conditions, such as bacterial vaginosis, remain prevalent and serious problems that can negatively impact a woman's quality of life and create economic burden for women, employers, and the broader healthcare system. Scientific evidence suggests that there may be benefits to following an effective primary bacterial infection treatment with administration of live bacterial cultures to rebalance the vaginal microbiota disrupted by the infection. It is believed that addressing the vaginal dysbiosis by reconstituting the vaginal microbiota could reduce recurrence and reduce susceptibility to other infections and conditions, including sexually transmitted infections and preterm labor and birth. A barrier to development of live biotherapeutic products for vaginal administration in low and middle income countries is the identification of a delivery vehicle capable of maintaining the viability of the live microbes during product storage, shipment and distribution.

"One of Daré's top priorities is to accelerate the development of differentiated products that can not only improve outcomes but increase access and convenience for women," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "We previously demonstrated the ability of a novel hydrogel technology to effectively deliver an active pharmaceutical ingredient vaginally through the development and approval of XACIATO™ (clindamycin phosphate) vaginal gel, 2%, our FDA-approved treatment for bacterial vaginosis in females 12 years of age and older for which global commercialization rights have been licensed to Organon. However, there remains a clear and unmet need for products that can be administered following effective treatment of the primary vaginal infection to then rebalance the vaginal microbiota and promote continued improved vaginal health. This grant will enable us to investigate the use of a novel hydrogel technology to deliver live biotherapeutics to address this challenge that affects women everywhere. We are grateful for the foundation's support in advancing this technology with the goal of making such therapies available to women worldwide."

On December 7, 2021, Daré announced that the U.S. Food and Drug Administration (FDA) approved the company's first application of a hydrogel technology with the approval of XACIATO™ (clindamycin phosphate) vaginal gel, 2% for the treatment of bacterial vaginosis in females 12 years of age and older. On June 30, 2022, Daré announced that the exclusive license agreement entered into on March 31, 2022 with Organon, a global women's healthcare company, became fully effective. Under the agreement, Organon licensed global rights to XACIATO. The first commercial sale of XACIATO is anticipated in the first half of 2023 in the U.S.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing 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 prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility, and vaginal and sexual health.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel, 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, 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®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. To learn more about XACIATO, Daré's full portfolio of women's health product candidates, and Daré's mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product and 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 and 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 in the Investors section of Daré's website.

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," "objective," or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements relating to the potential development of a reconstitutable vaginal thermosetting gel formulation for delivery of live biotherapeutics, the potential capabilities and benefits of such a gel formulation and any therapeutic product in which it may be used, and the expected timing of the first commercial sale of XACIATO. 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 those expressed or implied by the forward-looking statements in this press release, including, without limitation: Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product candidate; 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; Daré's dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; Daré's ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy and continue as a going concern; the loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events 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 to fulfill their contractual obligations to Daré; 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 or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré's product or product candidates, if approved, to gain market acceptance or obtain adequate coverage or reimbursement from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a product or 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 and product candidates; 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; product liability claims; governmental investigations or actions relating to Daré's product or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; 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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