Daré Bioscience Announces Grant to Support Development of a Novel Non-Hormonal Contraceptive Candidate and Expansion of Ovaprene® Pivotal Study Clinical Trial Sites

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- Grant funds will support activities that will aid in the identification and development of a novel non-hormonal intravaginal contraceptive product candidate.

- Grant will also provide funding to allow Daré to expand the number of clinical sites in the ongoing Ovaprene® pivotal study to accelerate the development timeline.

SAN DIEGO, Nov. 13, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today announced it entered into a grant agreement with the Bill & Melinda Gates Foundation for a grant of up to approximately $10.7 million to fund activities related to the identification and development of a novel non-hormonal intravaginal contraceptive product candidate and to add additional clinical sites to accelerate the ongoing Ovaprene® pivotal study.

“We are thrilled to receive this grant and to see the foundation’s continued commitment to invest in non-hormonal contraceptive methods,” said Sabrina Martucci Johnson, President and CEO at Daré Bioscience. “We believe that we are the right organization to move these innovative programs forward, given our extensive experience in the contraceptive space; in particular with novel non-hormonal product development, and our proven ability to advance development of differentiated product candidates that fulfill unmet needs in women’s health.”

In addition to support for the Ovaprene® clinical trial, the grant will also support activities to de-risk the development of a novel non-hormonal intravaginal contraceptive, suitable for and acceptable to women in low- and middle-income country (LMIC) settings who need or would prefer to use such a product to avoid an unplanned pregnancy.

“We are very pleased that the foundation also sees the potential of a novel non-hormonal intravaginal contraceptive,” said Liz Proos, VP of Product Development at Daré Bioscience. “We believe such a method could fill an important gap in contraceptive options globally, which would make a meaningful impact towards empowering women to take charge of their reproductive health.”

Daré will receive an initial payment of approximately $5.4 million under the grant agreement in 2024. Additional payments are contingent upon Daré’s achievement of development and reporting milestones specified in the grant agreement during the approximately 24-month term of the grant agreement.

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, sexual health, pelvic pain, fertility, infectious diseases, and menopause.

The first FDA-approved product to emerge from Daré’s portfolio of women’s health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, 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. Visit www.xaciato.com for information about XACIATO. 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, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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 Bioscience leadership has been named on the Medicine Maker’s Power List and Endpoints News’ Women in Biopharma 2022. In 2023, Daré's CEO was honored as one of Fierce Pharma’s Most Influential People in Biopharma for Daré’s contributions to innovation and advocacy in the women’s health space. Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal’s 2023 Best Places to Work Awards.

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 X (formerly 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,” “project,” “target,” “objective,” “on track,” 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 amount and timing of Daré's receipt of funds under the grant agreement, Daré's anticipated use of funds it receives, Daré's expectations with respect to the impact of the grant funding on the ongoing Ovaprene® pivotal clinical study and its plans to identify and develop a novel non-hormonal intravaginal contraceptive product candidate suitable for and acceptable to women in LMIC settings, the potential for U.S. Food and Drug Administration (FDA) approval of Ovaprene based on a single pivotal clinical study, the expectation that a product candidate, if approved, could be a first-in-category product, the potential market size and opportunity for a product candidate, if approved, and the potential for Daré's product candidates to demonstrate they are safe and effective for their respective target indications. As used in this press release, the description of a product candidate as "first-in-category" is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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, risks and uncertainties related to: the risk that Daré does not receive funding under the grant agreement in the anticipated amounts or on the anticipated timeline, or at all, including due to the foundation's ability to modify, suspend, discontinue any payment of grant funds or terminate the grant agreement in certain circumstances largely in the foundation's discretion; Daré's ability to achieve the product development and other milestones required for it to receive the milestone-based payments under the grant agreement; the Daré's ability to add new clinical study sites to the Ovaprene pivotal study and the ability of such additional study sites to enroll study subjects in a manner that accelerates the study timeline; 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; 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; 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 the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré's interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; 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; cybersecurity incidents 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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