Daré Bioscience Announces Grant Funding Installment to Support Further Development of Novel Contraceptive Technology DARE-LARC1

09-21-2023 at 8:00 AM EDT

SAN DIEGO, Sept. 21, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced it will receive a payment of approximately $4.5 million as the latest installment under a grant agreement to advance the development of Daré's investigational contraceptive DARE-LARC1 through nonclinical proof of principle studies and other IND-enabling work to allow for the submission of an Investigational New Drug (IND) Application with the FDA, approval of which will be required to commence testing in humans. Under the terms of the grant agreement, Daré may receive a total of up to approximately $49 million to support nonclinical development of DARE-LARC1. Daré received an initial $11.5 million payment in 2021 and aggregate payments of approximately $12.4 million in 2022 under the grant agreement. Additional payments are conditioned on the program meeting specified development and reporting milestones.

"The DARE-LARC1 product candidate is one of a number of novel contraceptive technologies being developed by Daré," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "In addition to advancing important pre-clinical activities to support the DARE-LARC1 program, we're also excited to continue the late-stage development of Ovaprene®, our investigational hormone-free monthly intravaginal contraceptive that is designed to be worn conveniently over multiple weeks, or one menstrual cycle. We are on track to begin patient enrollment in the fourth quarter of this year in the planned pivotal Phase 3 clinical trial of Ovaprene being conducted in collaboration with NICHD. According to market research, 90% of females in the U.S. ages 18-64 have used contraception at some point in their reproductive years and more than 75% have used more than one contraceptive method throughout their lifetime.[1] We believe that DARE-LARC1 and Ovaprene have the potential to address important and unique needs not currently being addressed by commercially available options, and we also believe that each has the potential to become a new and unique birth control option, potentially leading to a meaningful expansion of the already recognized 18 contraceptive categories."

Ovaprene® is an investigational hormone-free monthly intravaginal contraceptive in late-stage clinical development. The planned Phase 3 clinical study of Ovaprene is a multi-center, single arm, non-comparative, pivotal contraceptive study to evaluate Ovaprene's effectiveness as a contraceptive device along with its safety and usability. If successful, Daré believes this study will be the single registrational study required to support a premarket approval application (PMA) submission for Ovaprene with the U.S. Food and Drug Administration (FDA). The pivotal Phase 3 study will be conducted under a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health. In 2020, Daré entered into a license agreement with Bayer relating to the development and commercialization of Ovaprene in the United States, if approved by the FDA. Under the agreement, Daré received an upfront payment and access to Bayer's extensive clinical and market capabilities while retaining control over Ovaprene's development and regulatory approval process. Bayer received the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial being undertaken by Daré. Bayer, in its sole discretion, has the right to make the license effective by paying $20.0 million to Daré. Such license would be exclusive with regard to the commercialization of Ovaprene for human contraception in the U.S. and co-exclusive with Daré with regard to development. Daré will also be entitled to receive commercial milestone payments potentially totaling up to $310 million, in addition to double digit tiered royalties on net sales.

DARE-LARC1 is an investigational, pre-clinical stage contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option. The technology underpinning DARE-LARC1 is designed to store and precisely deliver therapeutic doses over months or years in a single implant and was originally developed at the Massachusetts Institute of Technology (MIT) by renowned researchers Robert Langer, Ph.D. and Michael J. Cima, Ph.D. DARE-LARC1 is designed to be a personal contraceptive system operated by the patient to deliver the birth control medication levonorgestrel on demand or on a predetermined schedule that can be activated or deactivated as desired. As part of the grant agreement, Daré agreed to make DARE-LARC1 and any other products resulting from the grant project available at an affordable price to people most in need within developing countries.

[1] Frederiksen, et al., Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage (Nov 03 2022), https://www.kff.org/womens-health-policy/report/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage/, accessed 18 September 2023

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, vaginal health, reproductive health, menopause, sexual health and fertility.

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. 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 (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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 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 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 Daré's expectation that it will receive a $4.5 million payment under the existing grant agreement relating to DARE-LARC1, Daré's plans and expectations with respect to Daré's product candidates, including anticipated advancement of preclinical development of DARE-LARC1, anticipated timing for commencement and conduct of a pivotal Phase 3 clinical study of Ovaprene and conduct of the study in collaboration with NICHD, Daré's expectation that, if successful, the planned Phase 3 clinical study of Ovaprene will support a PMA submission with the FDA, Daré's expectation that Ovaprene and/or DARE-LARC1 could be first-in-category contraceptive products, and the potential market size and opportunity for a contraceptive product candidate, if approved. 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: 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 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 development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; 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 loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, and public health emergencies on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including their potential impact on Daré's ability to timely commence, 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 impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth / Julia Weilman
Burns McClellan
lroth@burnsmc.com / jweilman@burnsmc.com
646.930.4406

OR

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Evoke Canale
jake.robison@evokegroup.com
619.849.5383

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.