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

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Daré Bioscience's DARE-LARC1 Platform Technology has Transformative Potential for Women's Health as well as in Treating a Broad Range of Diseases

Strategic Process Underway to Explore Partnering Opportunities for Additional Indications such as with GLP-1s for Obesity and Metabolic Disorders and Other Conditions Requiring Precise, Prolonged Treatment

SAN DIEGO, April 23, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced it will receive a payment of $1 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. To date, Daré has received payments totaling approximately $28.3 million. 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. "We believe that DARE-LARC1 has the potential to address important and unique needs not currently being addressed by commercially available options, and 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."

DARE-LARC1 is a potential new category of long-acting, reversible contraceptive (LARC). If successfully developed and approved, DARE-LARC1 could provide women with unparalleled control over the management of their fertility to better meet specific individual family planning goals and objectives. As with other types of LARC products, investigational DARE-LARC1 is intended to provide effective contraception for an extended period without requiring day-to-day effort. Unlike current LARC products, DARE-LARC1's innovative features include precision dosing, extended device duration and wireless control. DARE-LARC1 utilizes levonorgestrel, which is the active pharmaceutical ingredient in a number of FDA-approved birth control methods.

Earlier this year Daré announced that it achieved technological proof of concept for DARE-LARC1 and the underlying innovative drug delivery platform designed to store and precisely deliver therapeutic doses over months or years through a single device. That milestone reflects the drug delivery platform's potential to address the treatment burden for various conditions where treatment requires frequent dosing or regular injections.

The technology behind this drug delivery platform was originally developed at the Massachusetts Institute of Technology by renowned researchers Robert Langer, Ph.D. and Michael J. Cima, Ph.D. and was previously validated in a first-in-human study in osteoporosis patients using an earlier prototype. Daré has since made significant technological enhancements to the design and integration of custom electronics, hardware, and software to achieve drug delivery targets while incorporating user feedback to optimize form and function. Daré's progress has resulted in a highly versatile platform technology with potential to address meaningful unmet needs in reproductive health as well as other therapeutic areas including diabetes, obesity, and other conditions requiring precise and prolonged treatment.

To support development opportunities outside of the reproductive health category, including diabetes, obesity, and other conditions requiring precise and prolonged treatment, Daré is exploring strategic discussions with potential industry partners.

Key features of the implant technology include:

- **Precision dosing**: Unique design allows for precise dose timing and amount using individually addressable drug micro-reservoirs.
- **Extended duration and dosing interval control**: The ability to house up to hundreds of individual doses means a single device can provide dosing over months to years.
- **No external charging or recharging required**: A custom implant grade battery is designed to last for up to 20 years, depending on the application.
- **Upgradable platform**: Device software can be updated without removal or replacement of the implant.
- **Two-way communication**: Smart technology can respond wirelessly to queries from an external communication device to provide status updates, modify dosing, and deliver other application specific information.
- **Smartphone integration**: Platform can be paired with custom mobile apps designed for each application to create a personalized experience for the user.

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.

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. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023. 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 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 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," "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 $1 million additional payment under the grant agreement relating to DARE-LARC1, DARE-LARC1's potential as a safe and effective LARC product, the potential market opportunity for DARE-LARC1, if approved, the potential of the drug delivery technology underlying DARE-LARC1 to be utilized in products for the treatment of a broad range of diseases and conditions, and the potential for Daré to enter into strategic collaborations relating to the drug delivery technology. 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; 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.

Contacts:

Media and Investors on behalf of Daré Bioscience, Inc:
Camilla White / Simona Kormanikova
Dentons Global Advisors
DareBioscience@dentonsglobaladvisors.com / 1.212.466.6450

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