Daré Bioscience Announces Grant Award Supporting Development of Potential New Therapeutic Intervention for the Prevention of Idiopathic Preterm Birth

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Grant Funds Will Support Proof-of-Concept Target Validation Studies for Preclinical Development of a Potential New Approach for the Prevention and Treatment of Idiopathic Preterm Birth

Currently no FDA-Approved Product for the Treatment of Preterm Birth

SAN DIEGO, July 31, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced it was awarded a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) in the amount of approximately $385,000 to support activities related to the conduct and completion of proof-of-concept target validation studies in support of a potential new approach for the prevention and treatment of idiopathic preterm birth. Daré will collaborate with its sub awardee, the Lockwood Laboratory at the University of South Florida (USF) Morsani College of Medicine, on the grant-funded activities.

Preterm birth is defined as a live birth before 37 completed weeks of gestation.[1,2] Premature babies often have serious health problems. These problems can vary in severity and the earlier a baby is born, the higher the risk of health-related complications, including difficulty maintaining normal body temperature, difficulty breathing or feeding, and susceptibility to severe infections and brain disorders.[2,3]

"We continue to drive innovation in women's health and, in light of the FDA's recent decision to withdrawal its approval of the only product indicated to reduce the risk of preterm birth in women with a history of spontaneous preterm birth, we believe that developing new therapeutic options for pregnant women at risk of delivering preterm is an area of urgent unmet need," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We commend the NICHD for its commitment to advancing new innovation in this critical area of unmet need and look forward to collaborating with USF on this important new development program."

Under an exclusive option agreement with the University of South Florida Research Foundation, Inc. (USFRF), a nonprofit Florida corporation that is a direct support organization of USF, Daré has an exclusive right, and not an obligation, to elect to negotiate to acquire the exclusive worldwide rights to patents and know-how controlled by USFRF related to this research in the field of human reproduction during an option period which extends through this NIH-funded development project.

According to the World Health Organization (WHO), an estimated 13.4 million babies were born preterm in 2020.[4] Preterm birth complications were responsible for the deaths of approximately 900,000 children in 2019 and complications from preterm birth are the leading cause of death among children under 5 years of age.[4]

1. March of Dimes PeriStats™, Preterm Birth, accessed 28 July 2023. https://www.marchofdimes.org/peristats/data?reg=99&slev=4&top=3
2. Mayo Clinic, Diseases & Conditions, Premature birth, accessed 28 July 2023. https://www.mayoclinic.org/diseases-conditions/premature-birth/symptoms-causes/syc-20376730
3. WHO, Newsroom, Questions and answers, Newborn health: Challenges facing preterm babies, accessed 28 July 2023. https://www.who.int/news-room/questions-and-answers/item/newborn-health-challenges-facing-preterm-babies
4. WHO, Newsroom, Fact sheets, Detail, Preterm birth, accessed 28 July 2023. https://www.who.int/news-room/fact-sheets/detail/preterm-birth

About NICHD

NICHD funds research in areas relevant to normal and abnormal human development, including contraception, fertilization, pregnancy, childbirth, prenatal and postnatal development, childhood development through adolescence, intellectual and developmental disabilities, and rehabilitation medicine. For more information, visit http://www.nichd.nih.gov.

About USF and USFRF

USF supports economic development in the Tampa Bay region and the State of Florida by educating and training students for productive careers, by supporting research and technology transfer, and by providing information and scholarly resources needed by the community.

USFRF supports this mission and enhances the research activities of USF faculty, staff, and students. Through its programs, USFRF brings together the strengths of USF and the region to provide a critical interface that stimulates high-tech and biotech industries and creates jobs. USFRF, a not-for-profit, direct-support organization (DSO), owns and operates the USF Research Park, a community of science and technology researchers and entrepreneurs. USFRF also supports USF CONNECT and the Tampa Bay Technology Incubator (TBTI) on behalf of the university. For more information, visit https://www.usf.edu/research-innovation/rf/about-usfrf.aspx.

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 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 development of a new therapeutic product for the prevention and treatment of idiopathic preterm birth, Daré's receipt of funds under the NICHD grant award, and Daré's collaboration with USF and potential acquisition of an exclusive worldwide license from USFRF relating to the new development program for prevention and treatment of preterm birth. 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.

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