Daré Bioscience Announces Funding Award Notice from the National Institutes of Health (NIH) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to Support DARE-FRT1 Phase 1 Human Clinical Study for the Prevention of Preterm Birth

August 19, 2020

SAN DIEGO, Aug. 19, 2020 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc.** (NASDAQ: DARE), a leader in women's health innovation, today announced that it received a Notice of Award of a grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). The award will support the clinical development of its novel intravaginal ring (IVR), DARE-FRT1. DARE-FRT1 is designed to deliver bio-identical progesterone continuously over a 14-day period and is being developed as a more convenient treatment option for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization regimen.

Daré's IVR technology is designed to allow for sustained drug delivery over time periods ranging from weeks to months. Unlike other vaginal rings, Daré's IVRs feature a solid ethylene vinyl acetate (EVA) polymer matrix to contain and release a single or multiple active drugs without the need for a membrane or reservoir. DARE-FRT1 represents one of the potential unique applications of Daré's IVR technology in that it is designed to deliver non-oral bio-identical progesterone over multiple weeks without the need for daily administration, which has the potential to offer a better patient experience when compared to other delivery methods and may improve key aspects of treatment in terms of convenience and compliance.

"The World Health Organization (WHO) estimates that every year 15 million babies are born preterm, before 37 completed weeks of gestation, that this number is rising, and that complications from preterm birth are the leading cause of death among children under five years of age, equating to approximately one million deaths in 2015[1]," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We continue to strive to deliver against our mission of addressing persistent unmet needs in women's health, and based on the latest data from the WHO, it's clear that preterm birth is an area of continued and growing unmet need. We are grateful to the NICHD for its commitment to advancing new innovation in this important therapeutic area and look forward to advancing the development of DARE-FRT1 with the NICHD's support."

In July, Daré announced the initiation of a Phase 1 clinical trial of DARE-HRT1, a development-stage program utilizing the same IVR technology as DARE-FRT1 to deliver non-oral, bio-identical progesterone and estradiol for the treatment of menopausal symptoms.

"We believe the DARE-HRT1 Phase 1 study will provide important scientific information for both DARE-HRT1 and DARE-FRT1, given that they both utilize the same IVR technology and bio-identical progesterone as an active ingredient," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "Specifically, in the Phase 1 study of DARE-HRT1, we anticipate collecting useful pharmacokinetics characteristics of the bio-identical progesterone alone, which can be expected to directly apply to DARE-FRT1, and inform the work that the NICHD award will support."

Daré worked with Grant Engine on the development of its grant proposal to the NICHD. Grant Engine is regularly identified as a leading company to assist with federally funded grant opportunities, including through the Small Business Innovation Research (SBIR) program for the NIH, the Department of Defense, the Defense Advanced Research Projects Agency and others. Daré plans to continue to pursue non-dilutive funding opportunities to support the further development of its product candidates.

NIH funding is awarded in phases and Daré may be eligible to receive up to a total of approximately $2.3 million in grant funding for its DARE-FRT1 program based on the grant application it submitted to support the DARE-FRT1 Phase 1 human clinical study. The NICHD award granted to date of approximately $300,000 is for what is referred to as the "Phase I" segment of the project outlined in Daré's grant application, which is to occur during the period of August 2020 through July 2021. Additional potential funding of up to approximately $2 million for the "Phase II" segment of the project outlined in the grant application is contingent upon satisfying specified requirements, including, assessment of the results of the Phase I segment, determination that the Phase I goals were achieved, and availability of funds.

The content of this press release is solely the responsibility of Daré Bioscience, Inc. and does not necessarily represent the official views of the National Institutes of Health. This press release discusses a project that will be supported by Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health under Award Number R44HD101169.

[1] World Health Organization, Preterm birth key facts [accessed 2020 Aug 18], https://www.who.int/news-room/fact-sheets/detail/preterm-birth

About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
NICHD conducts and supports research in the United States and throughout the world on fetal, infant and child development; maternal, child and family health; reproductive biology and population issues; and medical rehabilitation. For more information, visit http://www.nichd.nih.gov.

About Grant Engine
Grant Engine principals are company builders first and last. Grant Engine helps leading companies build value through its proprietary process. The key principals have an excellent track record of building companies through non-dilutive funding as well as equity. For more information, visit grantengine.com.

About Daré Bioscience
Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's clinical-stage product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a hormone-free, monthly

contraceptive intravaginal ring 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®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. 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 may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations 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 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 on its investor relations website (https://darebioscience.gcs-web.com/) 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 on the investor relations page of Daré's website mentioned above.

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," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, the potential for DARE-FRT1 to provide a safe, effective and convenient treatment option for the prevention of preterm birth or broader luteal phase support as part of an in vitro fertilization regimen, the potential utility of Daré's IVR technology to address persistent unmet needs in women's health, the potential utility of the Phase 1 clinical study of DARE-HRT1 in the development of DARE-FRT1, Daré's plans to continue to pursue non-dilutive funding opportunities to support the further development of its product candidates, and the potential for Daré to receive up to approximately $2.3 million in total grant funding from the NICHD based on the grant application it submitted for DARE-FRT1. 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, risk and uncertainties related to: Daré's ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic 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, including its clinical trials, to fulfill their contractual obligations to Daré; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to conduct and design 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; the risk that positive findings 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; Daré's ability to retain its licensed rights to develop and commercialize a 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 candidates; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; 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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