Daré Bioscience Announces NIH Grant Award to Support Development of DARE-LARC1

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DARE-LARC1 Aims to Combine the Benefits of Long-acting Reversible Contraception with User-Controlled Flexibility to Pause or Resume Contraception as Desired

SAN DIEGO, Sept. 27, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced a Notice of Award of a grant from the Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD), a division of the National Institutes of Health (NIH), for $309,614. This grant will support the development of DARE-LARC1, Daré's investigational user-controlled, long-acting reversible contraceptive (LARC), and such funding is in addition to a separate unrelated grant award for this program of up to $48.95 million announced earlier this year.

"This commitment of funding from the NIH underscores the progress made to date on DARE-LARC1 and highlights the global unmet need for further innovation in long-acting, reversible contraceptive options for women," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience.

DARE-LARC1 is an investigational contraceptive implant currently in preclinical development. The technology underpinning DARE-LARC1 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 store and precisely deliver hundreds of therapeutic doses of the contraceptive levonorgestrel over a period of years and to be controlled by the user, without further intervention by a healthcare provider. DARE-LARC1's woman-centered design seeks to offer the benefits of traditional LARC products with the added flexibility and convenience for the user to pause and resume release of levonorgestrel, depending on her desire for fertility or contraceptive protection.

"The current FDA-approved LARCs offer high rates of contraception effectiveness over periods ranging from 3 to 10 years, however, they can be burdensome for women, requiring a physician to insert and subsequently remove the LARC in order to return to fertility. DARE-LARC1 seeks to improve upon this profile by enabling a woman to pause her contraception when she wishes to conceive and to subsequently resume contraception at a future time," said Elizabeth Proos, Vice President, Product Development for Daré Bioscience. "Our goal for DARE-LARC1 is to provide a level of contraceptive effectiveness comparable to other approved LARCs but without the need for multiple procedures to insert, remove and reinsert the device."

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 (DOD), the Defense Advanced Research Projects Agency (DARPA) and others. Daré plans to continue to pursue non-dilutive funding opportunities to support the further development of its product candidates.

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 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 www.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 product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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 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 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 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 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 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. In this press release, forward-looking statements include, but are not limited to, statements relating to Daré's receipt of grant funding for development of DARE-LARC1, continued development of DARE-LARC1, DARE-LARC1's potential to provide safe and effective user-controlled, long-acting reversible contraception and to address a significant unmet need in contraception, and Daré's plans to continue to pursue non-dilutive funding opportunities to support the further development of its product candidates. 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: the risk that Daré may not receive full funding of the grants awarded to support development of DARE-LARC1; 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 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; 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 developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; 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; Daré's failure to timely establish or leverage third-party partnerships or collaborations to commercialize its product candidates, if approved; 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; 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.

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 the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R43HD107685.

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