



Daré Bioscience receives notification of second award from the National Institutes of Health Eunice Kennedy Shriver National Institute of Child Health and Human Development for the development of Ovaprene®

March 11, 2019

SAN DIEGO, March 11, 2019 (GLOBE NEWSWIRE) -- [Daré Bioscience, Inc.](#) (NASDAQ:DARE), a leader in women's health innovation, today announced that it received a second Notice of Award of \$982,851, part of a grant providing up to \$1.9 million in the aggregate for Ovaprene® research from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a division of the National Institutes of Health (NIH). The first award under the grant was \$224,665. This second award, an additional \$982,851, followed the NIH's review of an interim data analysis and other results of the first phase of work. The award will be applied to important clinical development efforts supporting Ovaprene, a potential first-in-class hormone-free contraceptive solution. The remaining portion of the award under the grant, \$730,722, is contingent upon, among other matters, assessment that the results of the ongoing Ovaprene study satisfy specified requirements set out in the award notice, and the availability of funds.

"We are honored to continue to receive this non-dilutive funding to support the ongoing Ovaprene study," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "The second notice is well timed as we are actively enrolling couples in our pre-pivotal, postcoital test (PCT) clinical study and gathering data regarding Ovaprene's general safety, acceptability, and effectiveness in preventing progressively motile sperm from reaching the cervical mucus. The completion of the PCT clinical study will represent a significant milestone for Daré, and we currently expect to report topline data during the second half of 2019. If positive, we intend to submit an investigational device exemption (IDE) application to the U.S. Food & Drug Administration (FDA) in order to commence a pivotal contraceptive study of Ovaprene during 2020."

Ovaprene is a clinical stage, non-hormonal contraceptive ring intended to provide contraceptive protection for multiple weeks. It requires no intervention at the time of intercourse and fills a void in today's contraception alternatives. It represents a new approach to contraception and if approved, will offer women a convenient non-hormonal and non-invasive contraception method.

Daré worked with Grant Engine, a leading company in the Small Business Innovation Research program for the NIH, U.S. Department of Defense, Defense Advanced Research Projects Agency and other federal government funding opportunities, on the development of the grant proposal. Daré plans to continue to pursue non-dilutive funding opportunities to support the further development of its product candidates.

The content of this press release is solely the responsibility of Daré 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 and Human Development (NICHD) of the National Institutes of Health under Award Number R44HD095724.

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 Funding under the Grant

NIH funding is often distributed in phases. Phase I funding of the Ovaprene grant was \$224,665 and covered research and development activities from May 2, 2018 through October 31, 2018. Phase II funding of up to \$982,851 will cover approved activities from March 11, 2019 through February 29, 2020. The award of the last phase of funding of up to \$730,722 is contingent upon Daré satisfying specified requirements set out in the Phase II notice of award, including a determination that the Phase II goals were achieved, as well as an assessment of the project's commercialization and availability of funds.

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-class candidates in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive intravaginal ring; 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 uses these channels to communicate with its investors and the public about the company and other company-related matters. The information Daré posts on its investor relations website 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: www.darebioscience.com.

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, statements relating to: the potential to receive reimbursement for expenses incurred under the Phase II of the NIH grant; the potential to receive notification of award of the Phase III funding of the NIH grant; the completion of the PCT clinical study; expectations regarding the timing of reporting on data from the PCT clinical study; the intent to submit an IDE application to the FDA to commence a pivotal contraceptive study of Ovaprene and the timing thereof. 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; 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; 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:

Alex Gray
Burns McClellan
agray@burnsmc.com
212-213-0006

OR

Media on behalf of Daré Bioscience, Inc.:

Amanda Guisbond
Canale Communications
amanda@canalecomm.com
781-405-8775

Source: Daré Bioscience



Source: Dare Bioscience, Inc.