Daré Bioscience Announces NIH Grant Award

May 11, 2022

Supports research to define end-user preferences among U.S. women to inform the design of long-acting injectable hormonal contraception

Daré is developing novel injectable formulations of etonogestrel designed to provide 6- or 12-month contraceptive protection

SAN DIEGO, May 11, 2022 (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) of the National Institutes of Health (NIH) of approximately $249,000 to support end-user research, including surveys of approximately 1,000 women in the U.S. ages 18-44 years, to better understand women's preferences for a long-acting injectable (LAI) contraceptive method. The study will provide insights regarding duration preferences of users or potential users of LAI contraceptive products, how women evaluate LAI products against other contraceptive methods and the extent to which preferences will differ by age, socio-demographic characteristics, fertility intentions, reproductive history, and contraceptive history and general preferences. The findings of the study will also help to inform the characteristics of U.S. women most likely to be interested in using a LAI contraceptive method.

"The grant will enable Daré to better understand women's preferences, particularly with regard to the key features of LAI hormonal contraceptives," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "The findings from this study will inform our target product profile and guide our development priorities for ADARE-204 and ADARE-214. We are excited to be working with the Population Council on this important initiative and we are grateful to NICHD for its commitment to advancing new programs that have the potential to address unmet needs and offer a better experience for women."

This Notice of Award (Award Number R43HD108820) represents the third award that Daré has received from NICHD to inform or support the development of a contraceptive product candidate. Daré previously received grants from NICHD to support the development of DARE-LARC1, a long-acting, reversible personal contraceptive system in preclinical development, and Ovaprene®, an investigational hormone-free monthly contraceptive.

About Long-acting Injectable Contraception

Injectable hormonal contraception has been part of the method mix worldwide since the 1960s and in the U.S. since 1992. Currently, the maximum duration of protection available is three months with depot medroxyprogesterone acetate (DMPA) the most commonly used LAI product globally. Many women find injectables more convenient and discreet than taking a daily birth control pill, and some prefer this method to device-based longer-acting reversible methods (e.g., intrauterine devices; implants). While DMPA is over 99% effective when used properly, several features are believed to result in limited compliance and hence lower effectiveness at preventing pregnancy, including barriers associated with returning to the clinic every 3 months, side effects, including menstrual pattern changes, and longer-than-expected return to fertility up to 10 months. As such, one-year discontinuation rates can be as high as 60%.

About ADARE-204 and ADARE-214

In collaboration with Adare Pharma Solutions, Daré is developing long-acting injectable etonogestrel contraceptives with target 6- and 12-month durations (known as ADARE-204 and ADARE-214, respectively). Leveraging advances in microsphere technology developed by Adare Pharma Solutions that support extended release of etonogestrel with control over drug release rate, this preclinical-stage LAI program is targeting contraceptive protection for either 6- or 12-months, a rapid return of fertility within two months, a steadier hormone dose than currently available products, and anticipated side effects similar to the FDA-approved contraceptive etonogestrel implant. These targeted durations of pregnancy prevention are intended to fill a long-standing gap in the contraceptive market for products lasting between three months and three years, independent of user adherence.

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, fertility, and vaginal and sexual health.

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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also 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®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. 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 potential for the NICHD grant to enable research that provides Daré with a better understanding of women's preferences for a LAI contraceptive method and key features of such products; the potential for Daré to develop ADARE-204 and ADARE-214 as safe and effective LAI contraceptive products that women prefer to alternative contraceptive methods, and the potential for ADARE-204 or ADARE-214 to achieve the targeted product profile. 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 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; 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 loss of, or inability to attract, key personnel; the risks that a commercial or development collaborator may discontinue its interest in Daré's product or product candidate, fail to perform as expected or terminate the underlying agreement, or that any such agreement does not become fully effective; the risk that future payments to Daré under any out-license agreement may be significantly less than the anticipated or potential amounts; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events 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 to fulfill their contractual obligations to Daré; 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 or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product candidates, if approved; 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, product candidates or business activities; cyberattacks, 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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