Daré Bioscience Completes Recruitment in Pre-Pivotal Trial Of Monthly Woman-Controlled, Hormone-Free Contraceptive Candidate, Ovaprene®

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Ovaprene has the Potential to be the First FDA-Approved Monthly, Self-Administered, Hormone-Free Contraceptive

SAN DIEGO, Calif., June 26, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced completion of patient recruitment in its pre-pivotal, postcoital test (PCT) trial of Ovaprene®. Ovaprene is a self-administered, hormone-free, novel intravaginal ring, similar in size and shape to NuvaRing®. Ovaprene is designed to achieve contraceptive effectiveness over multiple weeks without the use of hormones and has the potential to be a first-in-category contraceptive, if approved. There currently is no FDA-approved, self-administered contraceptive that can provide month-to-month contraceptive protection without the use of hormones.

Ovaprene's proprietary design integrates a permeable polymer matrix barrier in the center of a small silicone ring with the release of a locally acting agent that impedes sperm motility. This unique dual approach of a physical barrier and spermiostatic environment is designed to provide a contraceptive effect consistent with the most effective barrier option, the diaphragm, and commonly used short-acting hormonal options (contraceptive pill, patches and vaginal ring), which provide 88-91% effectiveness in "typical use." All other commonly used or soon to be marketed hormone-free contraceptive products are used at, or shortly before, coitus (including condoms, spermicides, multi-purpose gels) and do not achieve "typical use" contraceptive effectiveness comparable to hormonal methods or are not self-administered (long-acting copper IUDs).

"We believe the positive data from a prior PCT trial published in the Journal of Reproductive Medicine, which demonstrated Ovaprene was successful at blocking sperm from entering the cervical canal, coupled with the high investigator and patient interest in this more robust pre-pivotal PCT trial that we have been conducting, suggest a significant market opportunity for a monthly, woman-controlled, hormone-free contraceptive," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience.

According to data from the Centers for Disease Control and Prevention (CDC), in 2015 to 2017, approximately 65% of the more than 72 million women of reproductive age (ages 15 to 49) in the U.S., or more than 46 million women, were currently using contraception. Non-discounted spending on prescription contraceptives in the U.S. has exceeded $5 billion annually.

Topline data from the Ovaprene PCT study are expected to be reported in the fourth quarter of 2019. If this PCT study demonstrates less than five progressively motile sperm per high powered field (< 5 PMS per HPF) in the cervical canal in most women and that Ovaprene can be safely worn over multiple weeks, Daré intends to prepare and file an Investigational Device Exemption (IDE) with the FDA to commence a pivotal clinical trial in women at risk for pregnancy.

About Ovaprene

Ovaprene is a clinical stage, woman-controlled, non-hormonal contraceptive ring intended to provide protection over multiple weeks of use, require no intervention at the time of intercourse, and create an viable new option in the hormone-free contraception method mix. It represents a new approach to contraception and, if approved, will represent a new birth control category.

About the PCT Clinical Trial

The PCT study (clinicaltrials.gov identifier: NCT03598088), which is being conducted with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health under Award Number R44HD095724, is designed to assess the ability of Ovaprene to prevent sperm from penetrating midcycle cervical mucus following intercourse and the general safety, acceptability and fit of Ovaprene in healthy, sexually active women who are not at risk for pregnancy due to previous female tubal sterilization. The study has a target of having at least 25 women complete a total of 21 visits. Women are evaluated over the course of five menstrual cycles, including a baseline measurement excluding the use of any product (during menstrual cycle 1), using a diaphragm (during menstrual cycle 2) and using Ovaprene (during menstrual cycles 3, 4 and 5).

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 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 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 the company's website mentioned above.

This press release includes information obtained from, and makes reference to, trade and statistical services and other third-party publications and sources. Daré has not independently verified such information and, although the company is not aware of inaccuracies in such third-party information, there can be no assurance as to its accuracy.

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 of Ovaprene to be the first FDA-approved monthly, self-administered, hormone-free contraceptive, the market opportunity for Ovaprene and the timing of reporting top-line data from the Ovaprene pre-pivotal PCT clinical trial. 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.:

Lee Roth
Burns McClellan
lroth@burnsmc.com
212-213-0006

OR

Media on behalf of Daré Bioscience, Inc.:

Jake Robison
Canale Communications
jake@canalecomm.com
619-849-5383

Source: Daré Bioscience

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