Daré Bioscience Announces Positive Findings from a Postcoital Test Clinical Study of Ovaprene® Hormone-Free Contraceptive Candidate

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- **Across all women and all cycles evaluated, Ovaprene prevented essentially all sperm from entering the cervical canal, a surrogate marker for contraceptive effectiveness.**
- **Currently marketed contraceptives with similar results in their PCT clinical studies subsequently demonstrated 6-month "typical use" effectiveness of 86-91% in their pivotal clinical trials, in the same range as traditional hormonal contraceptive methods.**

SAN DIEGO, Nov. 12, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced positive topline results from the Ovaprene postcoital test (PCT) clinical study, a multi-center, open-label, non-significant risk device pre-pivotal trial.

Ovaprene is a novel hormone-free monthly vaginal contraceptive, designed to offer both once-a-month convenience and "typical use" effectiveness in the same range as traditional hormonal contraceptive methods (pills, patches, vaginal rings). While the use of oral contraceptive pills has declined in recent years, the utilization of non-oral forms of contraception, including contraceptive rings or patches, has increased.[1] Worldwide sales of Merck's monthly, hormonal vaginal ring NuvaRing® were over $900 million in 2018.[2] The topline results from the PCT clinical study support continued clinical development of Ovaprene and its potential to be the first hormone-free, monthly contraceptive option for women.

"Market trends suggest there is a robust segment of women demanding alternatives to hormonal contraception and who prefer a once-a-month option,"[3] said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The PCT clinical study data, showing that Ovaprene prevented essentially all sperm from entering the cervical canal in 100% of women and 90% of women indicating they would recommend Ovaprene to a friend, are highly encouraging. These data give us confidence that Ovaprene has the potential to be an important new addition in the field of contraception and a much needed break-through product in the hormone-free category."

The PCT clinical study met its primary endpoint – Ovaprene prevented the requisite number of sperm from reaching the cervix across all women and all cycles evaluated. Specifically, in 100% of women and cycles, an average of less than five (< 5) progressively motile sperm (PMS) per high power field (HPF) were present in the midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place. To calculate the average number of PMS, PMS were counted across each of nine HPFs and averaged. Women enrolled in the study who completed at least one Ovaprene PCT (N=26) had a mean of 27.21 PMS/HPF in their baseline cycle (without any contraceptive device), a mean of 0.22 PMS/HPF in their diaphragm cycle (in the presence of an FDA-cleared diaphragm with spermicide), which was anticipated based on published studies, and a mean of 0.48 PMS/HPF in their Ovaprene PCT cycles (in the presence of the Ovaprene device), with a median of zero PMS. The table below summarizes these topline data in more detail.

	Mean	**Median**	**Standard Deviation**	**Interquartile Range**
Baseline PCT's	27.21	23.20	17.88	24.80
Ovaprene PCT's	0.48	0.00	1.18	0.10

No serious or severe adverse events were reported or observed.

"These data are highly significant and demonstrate that Ovaprene prevented almost all sperm from entering the cervical canal, a surrogate marker for highly effective contraceptives," said Christine Mauck, MD, Medical Director for Daré Bioscience. "Other contraceptives that demonstrated no motile sperm in the cervical mucus in PCT clinical studies of similar size, went on to demonstrate typical-use contraceptive effectiveness of 86-91% in pivotal studies evaluating pregnancy rates over six-month periods, similar in range to typical-use effectiveness rates of hormonal methods like pills, patches, and vaginal rings such as the NuvaRing® vaginal ring."

"The safety findings in the PCT clinical study are also reassuring in that they are typical of what we would expect in a standard diaphragm study. Notably, while a diaphragm is worn only during intercourse in a standard diaphragm study, Ovaprene was worn by participants in this study continuously for about three weeks in each of three cycles," continued Dr. Mauck.

"This study is the most robust PCT clinical study ever conducted in the field of contraception and these findings are encouraging with regard to Ovaprene's potential as an alternative to traditional hormone-based options. We are very encouraged by these findings," commented Andrea Thurman, MD, Professor of OBGYN at CONRAD/Eastern Virginia Medical School and a principal investigator in the Ovaprene PCT clinical study. "The potential opportunity to provide a hormone-free method that does not require intervention at the time of intercourse is compelling."

"The data from this study will be used to support an Investigational Device Exemption filing with the Center for Devices and Radiological Health, the division of the U.S. Food and Drug Administration that has been designated to review Ovaprene, under the FDA's premarket approval process," said Ms. Johnson. "Pending FDA review and clearance of the IDE, we plan to initiate a pivotal contraceptive effectiveness and safety study of Ovaprene in the second half of 2020. If successful, we expect that study to support marketing approvals of Ovaprene in the United States, Europe, and other countries worldwide. We also look forward to working with our investigators and collaborators on the PCT study to present its findings at a future

scientific conference."

1 - https://www.kff.org/womens-health-policy/fact-sheet/oral-contraceptive-pills/
2 - https://investors.merck.com/news/press-release-details/2019/Merck-Announces-Fourth-Quarter-and-Full-Year-2018-Financial-Results/default.aspx
3 - Hooper, DJ, Clin Drug Investig. 2010;30(11):74963

About the Ovaprene PCT Clinical Study

The Ovaprene PCT clinical study (clinicaltrials.gov identifier: NCT03598088), which was 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, was a multi-center, open-label, non-significant risk device study designed to assess the effectiveness of Ovaprene in preventing sperm from penetrating midcycle cervical mucus following intercourse and the general safety, acceptability and fit of the device in healthy, sexually active women who were not at risk for pregnancy due to previous female tubal sterilization. The primary endpoint of the study was to evaluate changes from baseline in PCT results due to device use as represented by the proportion of women and cycles with an average of fewer than five PMS/HPF in midcycle cervical mucus collected two to three hours after intercourse with Ovaprene in place.

The study enrolled 38 participants who completed a "baseline PCT cycle" (Cycle 1) in which at least five PMS/HPF were observed in the woman's cervical mucus after intercourse with no contraceptive device in place. All PCT tests in the study were performed at midcycle, as defined by a positive result on an ovulation predictor kit and a cervical mucus score of ≥ 10, based on the WHO scoring system, on specimens collected two to three hours after intercourse. Twenty-three participants completed a total of approximately 21 visits each. Following the baseline PCT cycle and enrollment, participating women were seen in four other menstrual cycles: Cycle 2, in which the cervical mucus was evaluated following intercourse with an FDA-cleared diaphragm used with spermicide; Cycle 3, in which no act of intercourse took place but Ovaprene was worn to collect safety, release, acceptability and fit assessment information; and Cycles 4 and 5, in each of which the cervical mucus was evaluated following intercourse with Ovaprene in place.

Daré collaborated with investigators from CONRAD, Oregon Health & Science University, the University of Pennsylvania, and a community clinic in Idaho Falls, ID to conduct the study.

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 hormone-free, monthly vaginal contraceptive; 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.

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 demonstrate typical-use contraceptive effectiveness in the same range as hormonal contraceptive methods (pills, patches, vaginal rings) and safety comparable to FDA-cleared diaphragms, the potential for Ovaprene to become the first FDA-approved hormone-free, monthly contraceptive option, women's contraceptive method preferences, the timing of a contraceptive effectiveness and safety clinical study of Ovaprene, the potential for regulatory approval to market Ovaprene in the U.S., Europe and other countries based on a single successful contraceptive effectiveness and safety clinical study, and the intent to present findings of the PCT clinical study of Ovaprene at a future scientific conference. 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; the risk that positive findings in pre-pivotal clinical studies of a product candidate may not be predictive of success in pivotal clinical 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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