



## Daré Bioscience Announces Publication of a Peer-Reviewed Journal Article Supporting the Use of the Postcoital Test Study as a Predictor of Contraceptive Effectiveness by *Biology of Reproduction*

June 24, 2020

Includes positive clinical findings from a postcoital test (PCT) human clinical study of Ovaprene®, an investigational hormone-free, monthly contraceptive

SAN DIEGO, June 24, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: [DARE](#)), a leader in women's health innovation, today announced the publication of a literature review article by *Biology of Reproduction* that identifies and reviews 10 postcoital test (PCT) studies of vaginal contraceptives involving 9 test products, including Daré's investigational hormone-free, monthly contraceptive Ovaprene, currently under a license agreement with Bayer for commercialization in the U.S.

The literature review was conducted with the support and participation of the Department of Obstetrics and Gynecology, University of Texas Medical Branch, Galveston, Texas, and Daré Bioscience. Based on the literature review, the article concludes that, for evaluating vaginal contraceptives, the PCT is the closest analogue available as a predictor of contraceptive effectiveness and is the best indicator of whether a test product works before it is evaluated in a contraceptive effectiveness study.

"The findings from our review clearly demonstrate that the PCT is predictive of contraceptive effectiveness, and that a test product that performs well in a PCT study carried out in the same manner as recent PCT clinical studies can be expected to demonstrate contraceptive effectiveness in a pivotal study at a level predictive of a highly effective contraceptive product," said Christine Mauck, MD, MPH, Medical Director for Daré Bioscience and co-author of the article. "We believe the Ovaprene PCT study completed by Daré last year is the most robust PCT clinical study ever conducted in the field of contraception, and the findings are encouraging in the context of other PCT studies with regard to Ovaprene's potential as an alternative to traditional hormone-based contraceptive options. As summarized in the article, other contraceptives that demonstrated PCT study results comparable to results seen with Ovaprene in last year's PCT study, went on to demonstrate six-month typical-use contraceptive effectiveness of 86-91% in their respective pivotal studies, which is similar in range to typical-use effectiveness rates of hormonal methods like pills, patches, and vaginal rings such as the NuvaRing® vaginal ring."

The accepted manuscript for the article entitled "The Postcoital Test in the Development of New Vaginal Contraceptives" is currently available in the Advance Articles section on the journal's website, or at <https://doi.org/10.1093/biolre/ioaa099>

Bayer and Daré Bioscience Exclusive Licensing Agreement for U.S. Commercial Rights to Ovaprene:

In January 2020, Daré announced that it entered into an exclusive licensing agreement with Bayer for U.S. commercial rights to Ovaprene. Under the agreement, Daré received an upfront payment and access to Bayer's extensive clinical and market capabilities while retaining control over Ovaprene's development and regulatory approval process. Bayer received the right to obtain exclusive rights to commercialize the product in the U.S. following completion of the pivotal clinical trial being undertaken by Daré. If Bayer, in its sole discretion, makes payment to Daré of \$20 million, which Daré intends to apply to reimbursement of clinical study costs, then the exclusive license to commercialize Ovaprene in the U.S. will become effective. Daré will also be entitled to receive commercial milestone payments potentially totaling \$310 million, in addition to double digit tiered royalties on net sales.

The PCT Study Background:

The PCT study was initially developed to assess whether cervical factors played a role in infertility and became standard practice in the evaluation of infertile couples for many decades until it was replaced in the 1990s by more predictive testing methodologies and the wider use of in vitro fertilization, which bypasses the cervical mucus-sperm interaction. The World Health Organization describes key aspects of the PCT procedure, including the timing for collection of cervical mucus after intercourse and the method of counting and characterizing sperm found in the mucus. [1] The PCT has been used to evaluate both chemical and mechanical barrier vaginal contraceptive products, including spermicides and diaphragms. [2, 3]

1. WHO laboratory manual for the Examination and processing of human semen, 5<sup>th</sup> ed., World Health Organization, 2010, available at <https://www.who.int/reproductivehealth/publications/infertility/9789241547789/en/>
2. A phase I randomized postcoital testing and safety study of the Caya diaphragm used with 3% Nonoxynol-9 gel, ContraGel or no gel. Mauck CK, Brache V, Kimble T, Thurman A, Cochon L, Littlefield S, Linton K, Doncel GF, Schwartz JL. *Contraception*. 2017 Aug;96(2):124-130.
3. The Postcoital Test in the Development of New Vaginal Contraceptives. Mauck CK, Vincent KL. *Biology of Reproduction*, 2020 June 16; accepted manuscript available at <https://doi.org/10.1093/biolre/ioaa099>

### 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 contraceptive intravaginal ring 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 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](http://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 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. Such statements include, but are not limited to, Ovaprene's potential as an alternative to traditional hormone-based contraceptive options, the potential of Ovaprene to demonstrate typical-use contraceptive effectiveness in a pivotal contraceptive safety and efficacy study comparable to current FDA-approved, highly effective contraceptive products, and potential payments and non-monetary benefits to Daré under its licensing agreement with Bayer. 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 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 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 risks that the license under the agreement with Bayer may not become effective and, if it becomes effective, that future payments to Daré under the agreement may be significantly less than the anticipated or potential amounts; the failure or delay in starting, conducting and completing clinical trials or obtaining U.S. Food and Drug Administration (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 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; 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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