



## **Dr. James Simon, Award-Winning Physician, Presents on Ovaprene® as a Promising Novel Non-Hormonal Contraceptive Method in Clinical Development**

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SAN DIEGO, April 15, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced Ovaprene's inclusion in a presentation to physicians on the latest forms of novel contraception. Ovaprene is Daré's clinical stage, non-hormonal vaginal ring designed to provide multiple weeks of contraceptive protection. The presentation entitled, "Contraception 2019: What about LARC, Rings, Gel, even Apps?", was given by noted physician and women's health expert Dr. James A. Simon during the Survival Skills for Today's Gynecologist continuing medical education conference in New York City on Sunday, April 14<sup>th</sup>. In Dr. Simon's presentation, Ovaprene was identified as a promising new method of contraception in clinical development based on its first-in-category potential as a non-hormonal, monthly birth control ring for women, and a product to watch in 2019 given that topline data from Ovaprene's postcoital test (PCT) clinical trial is expected later this year.

"The 'survival skills' forum provides an opportunity to present on a variety of important topics related to gynecological health and wellness, including emerging novel contraceptive methods," said James A. Simon, MD, President and Medical Director of IntimMedicine Specialists®, Clinical Professor at George Washington University School of Medicine, and current President of the International Society for the Study of Women's Sexual Health. "Since hormonal birth control can impact a woman's sexual functioning, a monthly non-hormonal option like Ovaprene has the potential to serve as a viable contraceptive that is both convenient and effective for women in need of new non-hormonal therapies."

Topline data from the Ovaprene PCT trial are expected in the second half of 2019. In a previous PCT trial, Ovaprene successfully prevented sperm from reaching the cervical canal.<sup>1</sup> The ongoing PCT clinical trial sponsored by Daré and supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, is designed to assess general safety, acceptability, and effectiveness in preventing most progressively motile sperm from reaching the cervical canal following intercourse, which is considered indicative of contraceptive effectiveness. If the PCT clinical trial demonstrates that Ovaprene is effective in preventing most progressively motile sperm from progressing into the cervical canal and is safe to use over multiple weeks, then Daré intends to prepare and file an Investigational Drug Exemption (IDE) with the FDA to commence a pivotal clinical study with Ovaprene in 2020.

"Dr. Simon's presentations at the Survival Skills conference highlighted the continued, persistent unmet needs across a variety of women's health conditions and the challenges women are facing when it comes to finding new and effective non-hormonal solutions," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience, Inc. "As the potentially first and only non-daily and non-implanted, hormone-free product in the category, Ovaprene has the potential to be an important and disruptive new entrant into a marketplace that has not seen a great deal of recent innovation. A non-hormonal contraceptive can also play an important role in preserving women's sexual functioning."

A review of recent studies pertaining to oral contraceptives and female sexual dysfunction published in *Sexual Medicine Reviews*, an official journal of the International Society for Sexual Medicine, linked the use of oral hormonal contraception to increased sexual dysfunction in women.<sup>2</sup> In addition to Ovaprene, Daré is developing Sildenafil Cream, 3.6%, a product candidate containing the same active ingredient in Viagra® that is being developed for the treatment of female sexual arousal disorder.

1. Journal of Reproductive Medicine 2009; 54: 685-690
2. [https://www.smr.jsexmed.org/article/S2050-0521\(16\)30022-1/pdf](https://www.smr.jsexmed.org/article/S2050-0521(16)30022-1/pdf)

### **About Ovaprene®**

Ovaprene is a novel vaginal ring that has the potential to become the first hormone-free monthly contraceptive approved by the U.S. Food and Drug Administration (FDA). Ovaprene's once-a-month format is designed to provide multiple weeks of contraceptive protection for the growing number of women seeking convenient, non-hormonal methods. In May 2018, a post-coital test (PCT) clinical trial was initiated to assess the safety and efficacy of Ovaprene in women over multiple weeks of use. Daré anticipates reporting topline data results from the PCT clinical trial in the second half of 2019. If safety and effectiveness are demonstrated in the ongoing PCT clinical trial, Daré intends to prepare and file an Investigational Device Exemption with the FDA to commence a single pivotal clinical trial. This pivotal trial would be expected to support marketing approvals of Ovaprene in the U.S., the EU, and other regions worldwide.

### **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](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.qcs-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 Ovaprene's potential to achieve regulatory approval and become a first-in-category contraceptive product, the timing of results from and commencement of clinical studies of Ovaprene, and the potential for a single pivotal clinical trial to support marketing approvals of Ovaprene in the U.S., the EU, and other jurisdictions. 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.*

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