Daré Bioscience Announces Commencement of Phase 3 Study of Ovaprene®, an Investigational Hormone-Free Monthly Intravaginal Contraceptive

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

SAN DIEGO, Dec. 04, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced commencement of the Company's pivotal Phase 3 clinical study of Ovaprene, an investigational hormone-free monthly intravaginal contraceptive.

The multi-center, single arm, non-comparative, pivotal Phase 3 clinical study of Ovaprene will evaluate its effectiveness as a contraceptive along with its safety and usability. The study aims to enroll sufficient participants across approximately 20 study sites in the U.S. to have approximately 250 participants complete approximately 12 months (13 menstrual cycles) of use, with updates on anticipated study completion expected as enrollment progresses. If successful, Daré expects the pivotal study to support marketing approvals of Ovaprene in the U.S. and other countries.

"While we've seen improvements in hormonal contraception over the last 20 years, many women need more options and innovation in non-hormonal contraceptive methods," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Ovaprene is a hormone-free monthly contraceptive that has disruptive, first-in-category potential based on its convenient use that doesn't require action at the time of intercourse and its unique mechanism of action, which based on the results of the pre-pivotal study, is expected to deliver efficacy approaching hormonal methods. Commencing our pivotal Phase 3 study marks an important milestone in the Ovaprene program as we strive to advance this innovative contraceptive option that women want and need."

In July 2021, Daré entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Health and Human Services, as represented by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health (NIH), to collaborate on the pivotal Phase 3 study of Ovaprene. The agreement gives Daré access to the contraceptive clinical trial expertise of the NICHD clinical trial network while also sharing the costs of the Phase 3 pivotal study with the NICHD.

In January 2020, Daré and Bayer announced an exclusive licensing agreement 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.

"We're excited about Daré's announcement of commencement of the pivotal Phase 3 clinical trial for Ovaprene," said Dr. Yesmean Wahdan, Vice President, US Medical Affairs Women's Healthcare at Bayer. "It is extremely important that we continue to innovate and strive to address women's unmet medical needs and wants, especially as it relates to contraceptive options."

If Ovaprene is approved by the U.S. Food and Drug Administration (FDA), it could be the first monthly non-hormonal contraceptive product for women and a first-in-category option for women in the U.S. seeking a hormone-free, self-administered and monthly birth control method.

About Ovaprene®

Ovaprene is an investigational hormone-free, intravaginal monthly product candidate currently in clinical development for pregnancy prevention. Ovaprene releases a locally acting, non-hormonal agent which impedes sperm motility and features a proprietary knitted polymer barrier to physically block sperm from entering the cervical canal.

Ovaprene completed a successful postcoital test (PCT) clinical study where, in all women and across all cycles evaluated, it prevented virtually all sperm from entering the cervical canal, a surrogate marker for contraceptive effectiveness.[1, 2] The 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.

[1] Mauck C, Vincent K. The postcoital test in the development of new vaginal contraceptives. *Biol. Reprod.* (August 2020); 103: 437–444. https://doi.org/10.1093/biolre/ioaa099

[2] ClinicalTrials.gov ID: NCT03598088, Safety and Acceptability Study of a Non-Hormonal Ring. (Results Posted)

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, vaginal health, reproductive health, menopause, sexual health and fertility.

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. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal 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 (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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 Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma 2022. In 2023, Daré's CEO was honored as one of Fierce Pharma's Most Influential People in Biopharma for Daré's contributions to innovation and advocacy in the women's health space. Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

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 X (formerly 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 Ovaprene's potential to be the first FDA-approved monthly, self-administered, hormone-free contraceptive product, Daré's expectation that Ovaprene will demonstrate efficacy approaching hormone-based birth control methods in its pivotal clinical study, Daré's expectation that the pivotal clinical study of Ovaprene, if successful, would serve as the primary clinical support for future applications for marketing approval in the U.S. and other countries, and the potential market opportunity for Ovaprene, if approved. 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, risks and uncertainties related to: 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; 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; 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 the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré's interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; 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 or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents 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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