Positive Interim Phase 3 Results Highlight Potential of Ovaprene®, Novel Hormone-Free Contraceptive

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Second Positive DSMB Review Supports Continued Study Progress

Interim Phase 3 Results Support Ovaprene's Differentiation as a First-in-Category, Hormone-Free, Intravaginal Monthly Contraceptive

SAN DIEGO, May 12, 2026 (GLOBE NEWSWIRE) -- **Daré Bioscience, Inc. (NASDAQ: DARE),** a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions, today announced positive interim safety and efficacy results from its ongoing Phase 3 clinical trial evaluating the contraceptive effectiveness, safety and acceptability of Ovaprene®, the company's investigational monthly, hormone-free intravaginal contraceptive. There currently are no FDA-approved, hormone-free, monthly intravaginal contraceptives.

The trial's independent Data Safety Monitoring Board (DSMB) conducted a planned interim analysis focused on reviewing safety data from the study, and recommended the study continue without modification.

The DSMB's findings and recommendation to continue the study are consistent with those from its prior interim analysis conducted in July 2025.

As was the case with the data presented to the DSMB in July 2025, these interim data show that approximately 9% of the women treated in the study had experienced a pregnancy, a rate consistent with the company's expectations based on the results of the pre-pivotal postcoital test clinical study of Ovaprene. These findings reinforce Ovaprene's potential as a meaningful hormone-free contraceptive alternative.

No new types of adverse events or tolerability concerns were identified. Neither an increase in the frequency of adverse events nor the emergence of new types of adverse events was observed with prolonged Ovaprene use. Approximately 12% of participants discontinued the study due to vaginal odor, the most commonly reported product-related adverse event – a 5% decrease compared to data reviewed by the DSMB in July 2025. No serious adverse events related to the study device were identified. A majority of participants who had completed the study reported they would be very likely or likely to use Ovaprene if it became available.

"We are encouraged by these interim results and this second positive DSMB review," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Millions of women in the U.S. are seeking effective, hormone-free birth control, and Ovaprene has the potential to address a significant unmet need and transform the contraceptive landscape. We look forward to advancing toward the primary endpoint analysis as we complete the study."

According to the FDA's birth control guide, the number of pregnancies expected using short-acting hormonal contraceptive methods—including oral contraceptives ("the pill"), the patch (transdermal system), and the vaginal ring—is seven per 100 women, and the number of pregnancies expected using male condoms is 13 per 100 women, and 17 per 100 women using diaphragms or sponges with spermicide.

For the interim analysis, the DSMB reviewed data from 339 study subjects, contributing 1,789 menstrual cycles of safety data, representing a meaningful proportion of the study's 2,500-cycle target. The ongoing pivotal Phase 3 trial is a multicenter, single-arm, open-label study enrolling women aged 18–40 across five sites. The study protocol calls for at least 2,500 cycles of exposure and at least 250 subjects completing 13 menstrual cycles of use. Based on current enrollment trends, the Company expects to achieve 2,500 cycles of exposure before 250 subjects complete 13 menstrual cycles of use. Interim safety data reviewed by the DSMB indicate that prolonged product use was not associated with the emergence of new types of adverse events or an increase in the frequency of adverse events, which the Company believes may support the sufficiency of fewer than 250 subjects completing 13 menstrual cycles of use to evaluate Ovaprene's safety profile. The Company intends to engage with FDA regarding these findings. The Company currently expects to complete enrollment sufficient to achieve at least 2,500 cycles of exposure in 2026. The primary objective of the study is to assess the typical-use pregnancy rate over 13 menstrual cycles, expressed as the Pearl Index, a standard measure of contraceptive effectiveness. Secondary objectives include assessment of Ovaprene's 13-cycle cumulative pregnancy rate, safety, acceptability, product fit/ease of use, and vaginal health. For more information about the study, please visit clinicaltrials.gov (ID # NCT06127199).

About Daré Bioscience

Daré Bioscience is a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions. Every innovation Daré advances is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, pelvic pain to fertility, vaginal health to infectious disease, Daré is working to close critical gaps in care using science that serves her needs.

For decades, women have been told to "wait it out" or "live with it," while innovations that could improve their quality of life languish in the regulatory or funding pipeline. With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting. However, access to real, evidence-based solutions continues to lag. Daré was founded to change that. As a female-led health biotech company, Daré is accelerating the development of credible, science-based solutions that meet the high standards of clinical rigor – randomized, controlled trials; validated endpoints; peer-reviewed publications; and current Good Manufacturing Practice (cGMP) requirements.

To learn more about Daré's mission to deliver differentiated therapies for women and its innovation pipeline, please visit www.darebioscience.com.

Daré Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma and Daré's CEO has been 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 may announce material information about its finances, products 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, and social media channels. 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, to follow Daré Bioscience, Inc. on LinkedIn, 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," "prepare," "seek," "should," "would," "target," "objective," "positioned," 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 as a safe and effective first-in-category, hormone-free, intravaginal monthly contraceptive, Ovaprene's potential to be the first U.S. Food and Drug Administration (FDA)-approved hormone-free, monthly intravaginal contraceptive, the importance of the interim results from the ongoing pivotal Phase 3 study of Ovaprene to Daré and Ovaprene, that enrollment in the study will be completed in 2026, that fewer than 250 subjects completing 13 menstrual cycles of use may support an evaluation of Ovaprene's safety profile, Daré's intention to engage with FDA regarding the study protocol, the anticipated timing of the primary endpoint analysis, and Ovaprene's potential, if approved, to address an unmet medical need in hormone-free contraception. As used in this press release, "first-in-category" is a forward-looking statement relating to the potential of a product candidate to represent a new category of product if it were to receive marketing approval for the indication for which it is being developed because Daré believes it would address a need in women's health that is not being met by existing FDA-approved products. 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: 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 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, completing or conducting clinical trials of a product candidate and the inherent uncertainty of outcomes of clinical trials; the potential that a product candidate in clinical development may never advance into or through a pivotal clinical study or obtain FDA or foreign regulatory approval; the risk that Daré's product candidates may fail to demonstrate acceptable safety and tolerability or sufficient efficacy in clinical trials; 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 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, including that fewer than 250 subjects completing 13 menstrual cycles of use is sufficient to support an evaluation of Ovaprene's safety profile; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; Daré's ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; Daré's dependence on grants and other financial awards from governmental entities and a private foundation; Daré's ability to maintain compliance with Nasdaq's continued listing requirements and continue to have its common stock listed on The Nasdaq Capital Market; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Daré's ability to raise additional capital or on Daré's operations, financial results and condition, and ability to achieve current plans and objectives;

the risk that the current regulatory pathway known as the FDA's 505(b)(2) pathway for drug product approval in the U.S. is not available for a product candidate as Daré anticipates; 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, pricing and reimbursement from third-party payors; 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 products 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; and cybersecurity incidents or similar events that compromise Daré's technology systems and/or significantly disrupt Daré's business or those of third parties on which Daré relies. 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 U.S. Securities and Exchange Commission, or 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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