Daré Bioscience Initiates Phase 2 Study of DARE-HPV, a Novel Pharmacologic Treatment for Persistent High-Risk HPV Infection with No FDA-Approved Therapies

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Each year, an estimated six million women in the United States acquire a high-risk HPV infection — and there are no FDA-approved treatments

DARE-HPV development is backed by a $10 million U.S. government (ARPA-H)-funded contract; topline data readout expected in 2027

SAN DIEGO, May 18, 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 the initiation of its Phase 2 clinical study of DARE-HPV, an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert, designed to evaluate DARE-HPV as a potential treatment for persistent high-risk human papillomavirus (HPV) infection.

DARE-HPV is being developed as a non-surgical, localized, self-administered therapy designed to clear persistent high-risk HPV infection. HPV infection is the underlying cause of 99% of cervical cancer cases in the United States. There are currently **no FDA-approved pharmacologic treatments** for HPV infection.

The Phase 2 study is a randomized, placebo-controlled, double-blind trial designed to evaluate the safety and antiviral activity of a lower and higher DARE-HPV dose compared with placebo in approximately 100 women with confirmed persistent high-risk HPV infection over an up to 21-day course of daily treatment. The primary endpoint is HPV clearance rate at three months post treatment. Secondary endpoints include safety, tolerability, and reduction in viral load. Daré Bioscience expects to report topline data in 2027. Study initiation follows clearance by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for the study, announced in February 2026, and represents a significant clinical development milestone.

By targeting the virus itself rather than waiting for cellular changes to develop, DARE-HPV has the potential to redefine the treatment paradigm in cervical disease prevention. If approved, DARE-HPV could be the **first FDA-approved pharmacologic treatment for HPV infection**, addressing a substantial unmet need, with more than 6 million women per year in the United States estimated to acquire a high-risk HPV infection.

"Initiating this Phase 2 study marks a historic step — for the first time, women with persistent high-risk HPV infection may have access to this pharmacologic treatment as part of a clinical trial," said Sabrina Johnson, President and CEO of Daré Bioscience. "For decades, women have been told to 'watch and wait' to see if the virus clears on its own or the infection progresses to precancerous lesions on the cervix. DARE-HPV is designed to intervene earlier – targeting the virus itself before progression to cervical disease – aiming to eliminate the frequent 'watchful waiting' visits to a health care provider that are costly, burdensome, and contribute to socioeconomic and racial disparities in cervical cancer. We are grateful to ARPA-H, our clinical investigators, and most importantly, to the women who will participate in this study."

HPV is one of the most common sexually transmitted viral infections worldwide. An estimated over 11 million women in the U.S. alone acquire a new HPV infection every year. While most HPV infections resolve spontaneously, an estimated 6 million of those women per year experience "high-risk" HPV infection, or an HPV infection caused by one of the carcinogenic HPV types, that can progress to precancerous cervical lesions and, ultimately, cervical cancer if left untreated. According to the Centers for Disease Control and Prevention, high-risk HPV types are responsible for nearly all cases of cervical cancer in the United States. Persistent high-risk HPV infection refers to testing positive for a high-risk HPV type at consecutive timepoints for at least 12 months.

Today, the standard of care does not treat the virus. Instead, women with high-risk HPV infection are monitored through repeated screening. Intervention typically occurs only after precancerous lesions develop, often requiring surgical procedures such as excisional or ablative treatments of cervical tissue. These procedures may increase the risk of preterm birth in future pregnancies and can pose risks to fertility – creating a significant physical and emotional burden for women.

Persistent high-risk HPV infection represents a substantial unmet medical need:

- High-risk HPV types cause virtually all cases of cervical cancer

- There are no FDA-approved pharmacologic treatments for high-risk HPV infection
- Current intervention strategies rely on surgical removal of abnormal cervical tissue
- Surgical procedures are associated with increased risks of preterm birth and potential impacts on fertility

The Phase 2 clinical study, as well as the broader DARE-HPV program, is supported by a **$10 million contract funded by the Advanced Research Projects Agency for Health (ARPA-H)**, part of the U.S. Department of Health and Human Services. Daré has received $9 million of this award to date and expects to receive the remaining funding as program milestones are achieved.

"This program reflects our commitment to advancing science where women have historically had limited or no therapeutic options," Johnson added. "With ARPA-H support and initiation of this Phase 2 study, we are positioned to generate clinical data that could meaningfully advance a product candidate with the potential to change how persistent high-risk HPV infection is managed."

Additional details regarding the Phase 2 study will be available at www.ClinicalTrials.gov. Daré Bioscience expects to report topline data from the Phase 2 study in the 2027 and will provide updates on study progress in the interim.

About DARE-HPV

DARE-HPV is an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert being developed as a non-surgical, localized, self-administered therapy for clearance of persistent high-risk HPV infection. Lopinavir and ritonavir are protease inhibitors with established antiviral activity. DARE-HPV development has been supported by a $10 million contract funded by ARPA-H. If clinically successful and approved, DARE-HPV could be the first FDA-approved pharmacologic treatment for HPV infection. There are currently no FDA-approved pharmacologic treatments for HPV infection.

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," "aim," "should," "would," "target," "advance," "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 DARE-HPV's potential as a safe and effective treatment for clearance of high-risk HPV infection, DARE-HPV's potential to be the first FDA-approved pharmacologic treatment for high-risk HPV infection, the conduct and completion of the Phase 2 clinical study of DARE-HPV and the timing of topline data from the study, the anticipated benefits of DARE-HPV, including its potential to reduce the incidence of cervical cancer in the U.S., the potential for DARE-HPV to redefine the treatment paradigm in cervical disease prevention, Daré's expectation of receipt of additional funding under its ARPA-H award, and the potential market opportunity for DARE-HPV, 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: failure or delay in

conducting or completing a clinical trial and the inherent uncertainty of outcomes of clinical trials; 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; 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 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 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, or that the duration of a study or number of study subjects must be significantly greater than anticipated; Daré's ability to achieve the milestones required for it to receive additional payments under its ARPA-H award; 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 products 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 products 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, 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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