Daré Bioscience Announces FDA Clearance of IND for Phase 2 Clinical Study of DARE-HPV, a Potential Treatment for Persistent High-Risk HPV Infection, the Most Common Cause of Cervical Cancer

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DARE-HPV development supported by $10 million ARPA-H contract; program targets major unmet need with no FDA-approved therapies

SAN DIEGO, Feb. 23, 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 that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for DARE-HPV, an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert, allowing initiation of a planned Phase 2 clinical study 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.

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.

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, millions of women experience persistent high-risk HPV infection, the type of HPV infection 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.

Today, the standard of care does not treat the virus. Instead, women with persistent 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.

"FDA clearance to proceed to Phase 2 represents an important regulatory milestone for DARE-HPV and for women who currently have no treatment options for persistent high-risk HPV infection," 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. If it does not, the only option has been surgery once precancerous changes appear. 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."

The planned Phase 2 study is expected to evaluate the safety and antiviral activity of DARE-HPV in women with persistent high-risk HPV infection. The program, including the planned Phase 2 clinical trial, 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, $6.5 million of which has been received to date.

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

"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 FDA clearance in hand, we are positioned to advance DARE-HPV efficiently into

Phase 2 and generate clinical data that could meaningfully change how persistent high-risk HPV infection is managed."

Daré Bioscience will provide additional details regarding the Phase 2 study design and anticipated timelines for study initiation, which the company is preparing for 2026, in the coming months.

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. 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, products 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," "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 plans and timing for initiating a Phase 2 clinical study of DARE-HPV, Daré's expectation of receipt of additional funding under its ARPA-H award to support development, including the planned Phase 2 study, of DARE-HPV, Daré's ability to advance DARE-HPV efficiently into Phase 2 and generate meaningful clinical data, DARE-HPV's potential as a safe and effective treatment for clearance of high-risk HPV infection, the potential for DARE-HPV to be the first FDA-approved therapy for high-risk HPV infection, the potential for DARE-HPV to redefine the treatment paradigm in cervical disease prevention, 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: Daré's ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; Daré's ability to achieve the product development and other milestones required for it to receive additional payments under its ARPA-H award; 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 risks 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 and that interim data or results from a particular clinical study do not necessarily predict the final results for that study; the potential that a drug product candidate in Phase 2 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; 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 reliance on third parties in conducting key aspects of its business, including manufacturing clinical study supplies and commercial product, conducting clinical trials and nonclinical studies, and commercializing products, and Daré's lack of control over those third parties' performance; difficulties or delays in establishing and sustaining relationships with third-party collaborators; 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; disputes or other developments concerning Daré's intellectual property rights; 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; changes in healthcare, pharmaceutical, consumer protection or privacy laws and regulatory policies; increased scrutiny from regulators; competitive product launches; a product's ability to gain market acceptance; product liability claims; 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; 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; 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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