Dare Bioscience Announces New U.S. Patent Strengthening DARE-HPV Program as a Potential First FDA-Approved Pharmacologic Treatment for HPV Infection

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New U.S. patent expands intellectual property foundation for DARE-HPV, a potential first-in-category treatment targeting persistent high-risk HPV infection

DARE-HPV Phase 2 study underway with topline results expected in 2027; program supported by approximately $10 million in non-dilutive ARPA-H funding and a $2.0 million NIAID award

DARE-HPV is designed to address a major treatment gap for the millions of U.S. women who experience high-risk HPV infection each year, for which there is currently no FDA-approved pharmacologic treatment

SAN DIEGO, Sept. 28, 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 issuance of U.S. Patent No. 12,678,439, titled "*Lopinavir and Ritonavir for the Treatment of Cervix Disorders*," which covers pharmaceutical compositions formulated for topical application comprising lopinavir and ritonavir for the treatment of HPV-related cervical pathologies.

The patent, issued by the United States Patent and Trademark Office on July 14, 2026, to Douglas Pharmaceuticals Limited, a licensor to Daré Bioscience, describes pharmaceutical compositions containing therapeutically effective amounts of lopinavir and ritonavir, including specific lopinavir-to-ritonavir weight ratios and formulations designed for topical administration. The patent includes claims directed to compositions for treating or inhibiting the development of early-stage neoplasias and for treating or preventing HPV-related cervical neoplasias. The patent is expected to provide protection into at least 2039.

"This patent adds another important layer to the foundation we are building around DARE-HPV at a particularly exciting point in the program's development," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Millions of women experience high-risk HPV infection each year in the United States, yet there is still no FDA-approved pharmacologic treatment to clear the infection. DARE-HPV is designed to change that paradigm with a localized, self-administered, non-surgical approach, and our Phase 2 study is now evaluating its potential to do exactly that. With clinical development underway, significant non-dilutive funding supporting the program, and an expanded intellectual property position, we believe DARE-HPV represents a compelling opportunity to address a significant unmet need in women's health and, if successful and approved, potentially establishing the first FDA-approved pharmacologic treatment for HPV infection."

The patent adds to the intellectual property landscape supporting the development of DARE-HPV, Daré Bioscience's investigational proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert being developed as a potential treatment for persistent high-risk human papillomavirus (HPV) infection. Daré holds an exclusive U.S. license to the patent described above and the broader patent family related to DARE-HPV under its 2023 license agreement with Douglas Pharmaceuticals Limited.

DARE-HPV is currently being evaluated in a Phase 2 randomized, placebo-controlled, double-blind clinical study in approximately 100 women with confirmed persistent high-risk HPV infection (ClinicalTrials.gov ID: NCT07601074). The study is designed to evaluate the safety and antiviral activity of lower and higher doses of DARE-HPV compared with placebo over an up to 21-day course of daily treatment, with HPV clearance at three months post-treatment as the primary endpoint. Topline results are expected in 2027.

DARE-HPV is being developed as a non-surgical, localized, self-administered therapy designed to clear persistent high-risk HPV infection. There are currently no FDA-approved pharmacologic treatments for HPV infection. Daré Bioscience's development of DARE-HPV is supported by approximately $10 million in non-dilutive funding from the Advanced Research Projects Agency for Health (ARPA-H) as Sprint for Women's Health awardee, and a $2.0 million award granted by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (Award Number R44AI188623).

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 potential non-surgical, localized, self-administered treatment for persistent high-risk HPV infection. Lopinavir and ritonavir are protease inhibitors with established antiviral activity. HPV infection is the underlying cause of virtually all cervical cancer cases in the United States. An estimated six million women per year in the United States experience high-risk HPV infection, for which there are currently no FDA-approved pharmacologic treatments. If clinically successful and approved, DARE-HPV could be the first FDA-approved pharmacologic treatment for HPV infection.

ABOUT DARÉ BIOSCIENCE, INC.

Daré Bioscience (NASDAQ: DARE) 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 Bioscience advances is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, sexual health to fertility, vaginal health to infectious disease, Daré Bioscience 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 proven solutions is lagging. Daré Bioscience is working to change that. Learn more at darebioscience.com.

FORWARD-LOOKING STATEMENTS

Daré Bioscience 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," "progress," "seek," "should," "would," "build" 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 a first-in-category treatment targeting persistent high-risk HPV infection and 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; the expected duration of patent protection into at least 2039; Daré Bioscience's expectation of receipt of additional funding under its ARPA-H award and NIAID award; and the potential market opportunity for DARE-HPV, if approved. 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 Bioscience 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 Bioscience'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 clinical trials 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 Bioscience'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 Bioscience's product candidates may fail to demonstrate acceptable safety and tolerability or sufficient efficacy in clinical trials; Daré Bioscience'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 Bioscience'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 Bioscience'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 Bioscience anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; Daré Bioscience's ability to achieve the milestones required for it to receive additional payments under its ARPA-H award and NIAID award; Daré Bioscience's dependence on grants and other financial awards from governmental entities and the risk that funding may be reduced, delayed, or terminated; Daré Bioscience's ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; Daré Bioscience'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 Bioscience's ability to raise additional capital or on Daré Bioscience's operations, financial results and condition, and ability to achieve current plans and objectives; the risk that the intellectual property landscape supporting DARE-HPV, including the newly issued patent and the licensed patent family, may not provide the expected scope or duration of protection, and the risk that patent protection may not extend into 2039 as currently expected; 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 Bioscience anticipates; the risk that developments by competitors make Daré Bioscience's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré Bioscience's products or product candidates, if approved, to gain market acceptance or obtain adequate coverage, pricing and reimbursement from third-party payors; Daré Bioscience's ability to retain its licensed rights to

develop and commercialize a product or product candidate; Daré Bioscience'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 Bioscience'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 Bioscience'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 Bioscience's products or product candidates or the business activities of Daré Bioscience, its commercial collaborators or other third parties on which Daré Bioscience 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 Bioscience's technology systems and/or significantly disrupt Daré Bioscience's business or those of third parties on which Daré Bioscience relies.

Daré Bioscience'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 Bioscience's risks and uncertainties, you are encouraged to review its documents filed with the U.S. Securities and Exchange Commission (SEC), including Daré Bioscience'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 Bioscience 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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