Daré Bioscience Selected to Receive $10 Million Award from ARPA-H's Sprint for Women's Health

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DARE-HPV is a potential first-in-category treatment for human papillomavirus (HPV)-related cervical disease which could change the treatment paradigm for clinical HPV management.

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SAN DIEGO, Oct. 23, 2024 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in innovation for the health and wellbeing of women, today announced that it has been selected by the Advanced Research Projects Agency for Health (ARPA-H) as an awardee of the Sprint for Women's Health to address critical unmet challenges in women's health, champion transformative innovations, and tackle health conditions that uniquely or disproportionately affect women. Daré will receive $10 million in funding over two years through the Sprint for Women's Health launchpad track for later-stage health solutions.

DARE-HPV is an innovative investigational treatment for HPV-related cervical disease. Essentially all cervical cancers worldwide are caused by HPV infection, and despite the advancements in HPV screening and vaccination, an estimated 100,000 women are still treated for cervical precancer and an estimated 4,000 women still die from cervical cancer in the U.S. every year. Today, cervical precancers are monitored until they reach a late stage, since the most common treatment is a surgery which removes part of the cervix; however, the surgery is associated with an increased risk of preterm birth and sexual dysfunction and therefore is not recommended for patients with fertility concerns.

"DARE-HPV has the potential to be the first FDA-approved pharmaceutical intervention that could treat both late-stage cervical lesions as well as earlier stage HPV-related cervical infections, which could change the paradigm around how HPV-related cervical diseases are clinically managed today," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We are thrilled that ARPA-H shares our vision for this product candidate's potential to transform the management of HPV-related cervical diseases with this at-home strategy to control the virus that causes cervical cancer."

ARPA-H sought solutions within six topics of interest in women's health, and received an unprecedented response of submissions. ARPA-H launched the Sprint for Women's Health in February, with First Lady Jill Biden announcing the funding as the first major deliverable from the White House Initiative on Women's Health Research.

The ARPA-H Sprint for Women's Health is conducted in collaboration with the Investor Catalyst Hub of ARPANET-H, the agency's nationwide health innovation network that connects people, innovators, and institutions to accelerate better health outcomes for everyone. Daré will work with an ARPA-H Program Manager and the Investor Catalyst Hub over two years to develop DARE-HPV, receiving milestone-based payments aligned to research activities and performance objectives.

The ARPA-H launchpad program accelerates transformative health solutions' path to impact by providing funding and market transition support. As a launchpad performer, Daré will also work with an Entrepreneur-in-Residence and participate in Launchpad Accelerator, which includes customized curriculum, virtual events, and in-person workshops to support performer market transition.

About HPV-Related Cervical Diseases and DARE-HPV

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. Essentially all cervical cancers worldwide are caused by infection with one of 14 carcinogenic, or "high-risk" HPV types (hrHPV). While some HPV infections are transient, persistent hrHPV infection can progress to cervical cancer through the persistence and progression of cervical lesions.

DARE-HPV is an investigational, proprietary fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert with the potential to be a first-in-category treatment for HPV-related cervical diseases. There currently are no U.S. Food and Drug Administration (FDA)-approved, non-surgical pharmaceutical interventions to treat high-grade cervical lesions (also called high-grade squamous intraepithelial lesions (HSIL) or high-grade cervical intraepithelial neoplasia (CIN 2/3)) and no FDA-approved treatments for HPV infection. DARE-HPV has the potential to be the first FDA-approved pharmaceutical intervention for the treatment of CIN and other HPV-related cervical pathologies.

In the U.S., about 10% of women with HPV infection on their cervix will develop long-lasting HPV infections that put them at risk for cervical cancer. The American Cancer Society estimates that approximately 13,820 new cases of invasive cervical cancer will be diagnosed and more than 4,000 women will die from the disease in the U.S. in 2024. Additionally, each year in the U.S., an estimated 100,000 people are treated for cervical precancer, of which approximately 74% are between the ages of 18–39 years, during prime childbearing and childrearing years.

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.

The first FDA-approved product to emerge from Daré's portfolio of women's health product candidates is XACIATO™ (clindamycin phosphate) vaginal gel 2%, 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. Organon commenced U.S. marketing of XACIATO in the fourth quarter of 2023. 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, the active ingredient in Viagra®, to treat female sexual arousal disorder (FSAD); 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 Daré's expectation that it will receive $10 million in funding from ARPA-H, DARE-HPV's potential as a safe and effective treatment for HPV-related cervical diseases, the potential for DARE-HPV to be the first FDA-approved pharmaceutical intervention for treatment of late-stage cervical lesions and other HPV-related cervical pathologies, and the potential market opportunity for DARE-HPV, if approved. As used in this press release, the description of a product candidate as "first-in-category" is a forward-looking statement relating to the potential of the candidate to represent a new category of product if it were to receive marketing approval for the indication for which Daré is developing it. 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 achieve the product development and other milestones required for it to receive payments under its ARPA-H funding award; 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 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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