Daré Bioscience Announces Start of a Phase 1 Study for its Potential First-in-Category Treatment for Primary Dysmenorrhea, DARE-PDM1

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SAN DIEGO, Feb. 22, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the start of a Phase 1 study evaluating its development program targeted at treating primary dysmenorrhea by delivering the active pharmaceutical ingredient diclofenac, a nonsteroidal anti-inflammatory drug (NSAID), in a novel way. Daré's investigational product, DARE-PDM1, will deliver diclofenac vaginally via the Company's proprietary hydrogel.

Primary dysmenorrhea is defined as painful menstruation in women with normal pelvic anatomy, typically described as cramping pain in the lower abdomen before or during the menstrual period. Recent market research suggests that the global market for dysmenorrhea treatment was estimated to be valued at USD $13 billion in 2022 and that the size of this market is expected to increase to USD $28.5 billion by 2029[1].

Oral NSAIDs, such as diclofenac, are often recommended for temporary relief from the painful symptoms of primary dysmenorrhea[2]. Because there are currently no FDA-approved vaginal diclofenac treatment options for primary dysmenorrhea, DARE-PDM1 has the potential to be a first-in-category product, delivering diclofenac in a convenient vaginal format that may extend the duration of pain relief and reduce the risks associated with the oral delivery of NSAIDs.

"The potential benefits of DARE-PDM1 as a potential treatment for the millions of women suffering from primary dysmenorrhea are driven by its unique target product profile," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Its key attributes include the utilization of a well-known and well-characterized active pharmaceutical ingredient for the condition, delivery of the active utilizing our novel hydrogel delivery technology which is designed to keep the product from leaking out of the vagina and may increase the vaginal residence time and, most importantly, the opportunity for local vaginal administration to reduce the frequency and severity of systemic side effects associated with commonly recommended and prescribed oral medications, such as oral NSAIDs and oral hormone contraceptive products."

Primary dysmenorrhea usually begins during adolescence and is a leading cause of recurrent short-term school absence in adolescent girls and a common problem in women of reproductive age. According to the American College of Obstetricians and Gynecologists' Committee on Adolescent Health Care, dysmenorrhea is the most common menstrual symptom among adolescent girls and young women, and most adolescents experiencing dysmenorrhea have primary dysmenorrhea. Prevalence rates of dysmenorrhea vary but range from 50% to 90%. A prospective study of college students found that 72% of monitored periods were painful, most commonly during the first day of menses, and 60% of the women studied reported at least one episode of severe pain.

"The most common interventions for primary dysmenorrhea include oral NSAIDs and hormonal contraceptives which often can produce undesirable side effects. Oral NSAIDs, which are available over the counter, may cause an increased risk of gastrointestinal adverse events, including nausea, vomiting, bloating or ulcerations, and hormonal contraceptives can often produce a number of undesirable side effects," said Dr. Annie Thurman, Medical Director of Daré Bioscience. "Local drug delivery through the vaginal mucosa allows lower doses that specifically target local genital tissues and the myometrium. By leveraging a vaginal route of administration, we believe we can provide a treatment option that addresses the pain-related symptoms of the condition while minimizing side effects commonly seen with use of oral medications."

The DARE-PDM1 Phase 1 study, DARE-PDM1-001, is a multi-center, randomized, placebo-controlled, double-blind, 3 arm parallel group study of approximately 36 healthy, premenopausal women with primary dysmenorrhea. This study is designed to assess the systemic (plasma) and local mucosal (vaginal fluid) diclofenac pharmacokinetics (PK) and safety after a single dose and during three daily doses of vaginally administered DARE-PDM1, given in two different strengths (1% or 3% diclofenac in 2.5 mL of hydrogel) versus placebo. The study will also assess, as an exploratory endpoint, the preliminary dysmenorrhea treatment efficacy of DARE-PDM1, when dosed in three daily doses at the onset of dysmenorrhea symptoms, compared to a no-treatment, baseline, control cycle. The study observation period will encompass approximately three menstrual cycles.

The DARE-PDM1-001 study will be conducted in Australia by the company's subsidiary, DARE Bioscience Australia Pty Ltd.

At the conclusion of the development program, if successful, Daré intends to leverage the existing safety and efficacy data for diclofenac to utilize the U.S. Food and Drug Administration's (FDA) 505(b)(2) pathway to obtain marketing approval of DARE-PDM1 in the U.S.

1. https://www.reanin.com/report-store/healthcare/pharmaceuticals-and-therapeutics/dysmenorrhea-treatment/global-dysmenorrhea-treatment-market
2. https://my.clevelandclinic.org/health/drugs/11086-non-steroidal-anti-inflammatory-medicines-nsaids

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, fertility, and vaginal and sexual health.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel, 2% is 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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. 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 to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. 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 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 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 plans and expectations with respect to DARE-PDM1 and its potential benefits, the anticipated conduct of the Phase 1 study for DARE-PDM1, the potential for DARE-PDM1 to be a first-in-category product, expectations regarding the future market size for dysmenorrhea treatment, and the potential regulatory approval pathway for DARE-PDM1. 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 those expressed or implied by the forward-looking statements in this press release, including, without limitation: 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; 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; Daré's dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; 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 is significantly greater than anticipated; 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; the loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions such as inflation, rising interest rates and geopolitical events on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely commence, enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business to fulfill their contractual obligations to Daré; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; 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; cyber attacks, security

breaches 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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