Daré Bioscience Initiates Phase 1/2 Clinical Study of DARE-VVA1, Intravaginal Tamoxifen for the Treatment of Vulvar and Vaginal Atrophy

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Investigational therapy for women who cannot, or should not, take supplemental estrogen

Potential to be the first treatment for vulvar and vaginal atrophy specifically developed for patients with hormone receptor-positive breast cancer, if approved

SAN DIEGO, Sept. 23, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the initiation of a Phase 1/2 clinical study of DARE-VVA1, a novel intravaginal tamoxifen product being developed for the treatment of moderate to severe vulvar and vaginal atrophy (VVA). The randomized, double-blind, placebo-controlled study is designed to evaluate the safety, pharmacokinetics and pharmacodynamics of DARE-VVA1 in postmenopausal participants with moderate to severe VVA and is being conducted by the company's wholly owned subsidiary in Australia.

"Vulvar and vaginal atrophy is an inflammation of the vaginal epithelium associated with lower estrogen levels as a result of menopause and certain cancer treatments and its symptoms adversely impact quality of life for women. Today, therapies for VVA are predominantly based on estrogen; however, there is a large unmet need for a novel non-hormonal VVA treatment specifically developed for women who have VVA as a result of treatment for hormone receptor-positive breast cancer, as well as for other women, who require or prefer a treatment option for VVA that does not contain estrogen," said Sabrina Martucci Johnson, Daré's President and Chief Executive Officer. "We're encouraged by an exploratory study of intravaginally administered tamoxifen published in *Clinical and Experimental Obstetrics and Gynecology* , that demonstrated improvements in vaginal pH and vaginal dryness without significant systemic absorption of tamoxifen in postmenopausal women with VVA,[1] together with studies of tamoxifen conducted over the last 40 years that have documented its estrogen-like effects on the vaginal epithelium. We're excited for the clinical advancement of DARE-VVA1 as a potential non-hormonal treatment alternative for this population."

The Phase 1/2 study will evaluate different doses of DARE-VVA1, a tamoxifen vaginal insert, in approximately 40 postmenopausal women with VVA, including a cohort of women with a history of breast cancer. The study is a randomized, multi-center, double-blind, parallel-arm, placebo-controlled, dose-ranging study that will evaluate the safety, tolerability, plasma pharmacokinetics (PK) and pharmacodynamics (PD) of DARE-VVA1. Eligible participants will be randomly allocated to one of five treatment groups (approximately 8 participants per group) that will evaluate four dose levels (1 mg, 5 mg, 10 mg, and 20 mg) and a placebo. Following a screening visit, DARE-VVA1 will be self-administered intravaginally once a day for the first two weeks, and then twice a week for the following six weeks for a total treatment period of 56 days. In each treatment group, participants will have serial blood sampling for PK analysis and undergo safety evaluations and preliminary assessments of effectiveness. Following the completion of the treatment period, participants will attend a safety follow-up visit.

The primary endpoints of the study will evaluate the safety and tolerability of DARE-VVA1 by vaginal administration and determine the plasma PK of DARE-VVA1 after intravaginal application. Secondary endpoints will evaluate preliminary efficacy and PD of DARE-VVA1 in terms of most bothersome symptom and changes in vaginal cytology and pH.

"Women navigating breast cancer treatment face many challenges and hardships in addition to those we commonly think about, including VVA," said James A. Simon, MD, CCD, NCMP, IF, FACOG, Clinical Professor of Obstetrics and Gynecology at The Washington University School of Medicine, and Medical Director and Founder of IntimMedicine Specialists®. "Having a safe and effective, non-hormonal therapy to address the uncomfortable symptoms of VVA could offer both physical and psychological benefits to patients and survivors. I look forward to following the progression of DARE-VVA1 as a potential first-in-category hormone-free vaginal treatment for VVA."

About Vulvar and Vaginal Atrophy (VVA)

VVA is an inflammation and thinning of the vaginal epithelium due to the reduction in levels of circulating estrogen. Typical symptoms include vaginal dryness, itching, burning, and painful intercourse, adversely impacting quality of life. VVA is a common condition in postmenopausal women and women with, or with a history of, hormone receptor-positive (HR+) breast cancer. Many breast cancer survivors experience menopausal symptoms irrespective of age as a direct consequence of their cancer treatment. Breast cancer patients treated with aromatase inhibitors refer to VVA as one of the most unpleasant side effects of treatment.[2]

Approximately 10 percent of women in the U.S. will develop breast cancer. The prevalence of VVA in postmenopausal breast cancer patients is estimated to be between 42 and 70 percent.

Products containing estrogen are commonly used to treat VVA. However, the use of estrogen-containing products for the treatment of VVA may be contraindicated for HR+ breast cancer patients and survivors because of the concern that estrogen use will promote recurrence of disease.[3]

About DARE-VVA1

DARE-VVA1 is an investigational, proprietary formulation of tamoxifen for intravaginal administration with the potential to be a first-in-category treatment of VVA for women with or at-risk of HR+ breast cancer. Tamoxifen is a well-known and well-characterized selective estrogen receptor modulator (SERM) that has been prescribed by oncologists for decades for the treatment of breast cancer. In breast tissue, tamoxifen acts as an estrogen antagonist. In contrast, in other tissues such as vaginal tissues, tamoxifen has been reported to exert an estrogen-like response on vaginal cytology. Studies of tamoxifen conducted over the last 40 years have documented its estrogen-like effects on vaginal epithelium. Localized tamoxifen therapy such as DARE-VVA1 thus has the potential to counter the physiologic changes that lead to VVA without introducing estrogen back into the system.

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone therapy following menopause. To learn more about Daré's full portfolio of women's health product candidates, and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, 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 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 on the investor relations page of Daré's website mentioned above.

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," "tend to," 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 the conduct of Phase 1/2 clinical study of DARE-VVA1 and DARE-VVA1's potential as a safe and effective therapy for VVA, including for HR+ breast cancer patients and survivors. 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, risk and uncertainties related to: Daré's ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic 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 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, including its clinical trials, to fulfill their contractual obligations to Daré; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; 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; the risk that developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a 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 candidates; Daré's failure to timely establish or leverage third-party partnerships or collaborations to commercialize its

product candidates, if approved; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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; 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.

Footnotes:

[1] J. Chollet, L. A. Meyn, F. Mermelstein. Weekly vaginal administration of tamoxifen for three months in postmenopausal women with vulvar and vaginal atrophy: a possible new treatment approach?. Clinical and Experimental Obstetrics & Gynecology, 2019, 46(2): 285-288. DOI: 10.12891/ceog4948.2019

[2] Biglia N., Bounous V.E., D'Alonzo M., Ottino L., Tuninetti V., et al. Vaginal Atrophy in Breast Cancer Survivors: Attitude and Approaches Among Oncologists. Clin. Breast Cancer, 2017 Dec; 17(8):611-17. DOI: https://doi.org/10.1016/j.clbc.2017.05.008

[3] American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice. The Use of Vaginal Estrogen in Women With a History of Estrogen-Dependent Breast Cancer. Committee Opinion No. 659, March 2016 (Reaffirmed 2020). https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2016/03/the-use-of-vaginal-estrogen-in-women-with-a-history-of-estrogen-dependent-breast-cancer.pdf

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