Daré Bioscience Announces Publication of Phase 1/2 Pharmacokinetic, Safety and Pharmacodynamic Data for DARE-VVA1 - a Potential New Hormone-Free Treatment for Vulvovaginal Atrophy - in Climacteric, the Journal of the International Menopause Society

June 9, 2023

SAN DIEGO, June 09, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the publication of results of its Phase 1/2 clinical study of DARE-VVA1, a proprietary, investigational formulation of tamoxifen for intravaginal administration to treat vulvovaginal atrophy (VVA) in women without the use of hormones. The journal article, "Pharmacokinetics, safety and preliminary pharmacodynamic evaluation of DARE-VVA1: a soft gelatin capsule containing tamoxifen for the treatment of vulvovaginal atrophy," was published online and will appear in *Climacteric*, the official journal of the International Menopause Society. The randomized, double-blind, placebo-controlled study was designed to evaluate the pharmacokinetics, safety and pharmacodynamics of DARE-VVA1 in postmenopausal participants with moderate to severe VVA.

"We are excited to have this peer-reviewed article published in the International Menopause Society's journal, *Climacteric*, and share our findings with the broader women's health community," said Andrea Thurman, MD, Medical Director for Daré Bioscience and lead author of the journal article. "The data from the study demonstrated safety and tolerability of our investigational product DARE-VVA1, as well as showed an improvement in vaginal cytology parameters and the bothersome vaginal symptoms commonly associated with VVA."

Daré is developing DARE-VVA1 as a new hormone-free treatment option to address moderate to severe VVA. If successful, DARE-VVA1 has the potential to be an important therapeutic for the treatment of VVA for women currently or previously treated for hormone-receptor positive (HR+) breast cancer and for other women who would like a vaginal, non-hormonal option for VVA treatment.

Globally, breast cancer is the most frequently diagnosed cancer type, accounting for over two million cases each year. Approximately 4 million U.S. women have a history of invasive breast cancer, and of all breast cancer diagnoses in U.S. women, it is estimated that more than 68% are HR+. VVA prevalence in postmenopausal breast cancer survivors is estimated at 42% to 70%.

"The unmet need for an effective non-hormonal treatment for VVA caused by anti-cancer endocrine therapy in patients diagnosed with HR+ breast cancer is undeniable. The current lineup of estrogen-based therapies, commonly used to treat VVA in non-cancer patients, can be challenging for both HR+ breast cancer patients and their providers as the use of estrogen products, in any form, is often contraindicated for the HR+ breast cancer patient population," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience. "If we are successful, vaginally-administered, hormone-free DARE-VVA1 will offer patients and providers an important new treatment option to address one of the most common vaginal side effects associated with breast cancer therapy."

The journal article is available online: https://doi.org/10.1080/13697137.2023.2211763

In November 2022, Daré announced positive topline results from the Phase 1/2 clinical study of DARE-VVA1.

Daré is conducting activities to support submission of an Investigational New Drug (IND) application and initiation of a Phase 2 clinical study of DARE-VVA1.

About Vulvovaginal 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, 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. The prevalence of VVA in postmenopausal breast cancer patients is estimated to be between 42 and 70 percent.

Commonly used therapies for VVA are estrogen based and are often contraindicated in HR+ breast cancer patients, or patients with a genetic predisposition or history of familial disease, because of the concern that estrogen use will promote recurrence or occurrence of disease.

About DARE-VVA1

DARE-VVA1 is an investigational, proprietary formulation of tamoxifen for intravaginal administration. Daré is developing DARE-VVA1 as a hormone-free alternative to estrogen-based therapies for the treatment of moderate to severe VVA. 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. Tamoxifen has unique properties that produce different effects (estrogen agonist or estrogen antagonist) in different types of tissues. In breast tissue, tamoxifen acts as an estrogen antagonist, meaning that it can inhibit estrogen's effect and hence why it may be effective in treating HR+ breast cancer. In contrast, in other tissues such as vaginal tissues, tamoxifen has been reported to elicit an estrogen-like response. This has the potential to have a favorable effect 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 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.

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 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 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 DARE-VVA1's potential as a safe and effective therapy for VVA, DARE-VVA1's potential to be a VVA treatment option for the HR+ breast cancer population, the potential market opportunity for DARE-VVA1, the importance of the results of the Phase 1/2 clinical study to Daré and DARE-VVA1, and the anticipated regulatory approval pathway and next steps for development of DARE-VVA1. 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, 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 the COVID-19 pandemic, macroeconomic conditions 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:

Lee Roth

Burns McClellan

lroth@burnsmc.com

646.930.4406

OR

Media on behalf of Daré Bioscience, Inc.:

Jake Robison

Evoke Canale

jake.robison@evokegroup.com

619.849.5383

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.