Daré Bioscience Announces FDA Clearance of Investigational New Drug (IND) Application for DARE-VVA1, a Novel Intravaginal Formulation of Tamoxifen for Moderate to Severe Dyspareunia, a Symptom of Vulvar and Vaginal Atrophy Associated with Menopause

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DARE-VVA1 has the potential to be the first therapeutic non-hormonal vaginal option for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA) in women who cannot or should not take supplemental estrogen

SAN DIEGO, Dec. 07, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for DARE-VVA1, a novel intravaginal proprietary formulation of tamoxifen being developed as a non-hormonal treatment option for moderate to severe dyspareunia, a symptom of VVA associated with menopause. With the IND clearance from the FDA, Daré can begin planning for an anticipated Phase 2 randomized, double-blinded, placebo-controlled, dose-finding clinical study of DARE-VVA1.

VVA is an inflammation and thinning of the vaginal epithelium due to chronic hypo-estrogenism, which is the reduction in levels of circulating estrogen. Typical symptoms include vaginal dryness, itching, burning, and painful intercourse (dyspareunia), adversely impacting quality of life. VVA most commonly occurs in postmenopausal women, in whom the prevalence is over 50% but survey data indicate only 56% of women experiencing menopausal vaginal changes discuss these symptoms with healthcare professionals, highlighting that the syndrome is often underdiagnosed. Products containing estrogen are commonly used to treat VVA but some women cannot or choose not to use these products, including those with a history of hormone-receptor positive (HR+) breast cancer.

"Although localized estrogen therapy is effective in reducing the symptoms of VVA and is commonly prescribed, there remains a large unmet need for non-hormonal treatment options for symptoms of VVA for women who cannot or choose not to use estrogen-based products," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "While we do not plan to commence the Phase 2 study until after we secure additional capital, this IND clearance marks an important regulatory step for Daré that supports our strategic discussions as we advance our portfolio of innovative product candidates and strive to address some of women's most persistent unmet needs."

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 dyspareunia, a symptom of VVA. Therapies containing estrogen 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. 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 elicit 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 underlying 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. 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 (FSAD) and/or female sexual interest/arousal disorder (FSIAD) 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 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 DARE-VVA1's potential as a safe and effective therapy, and the first non-hormonal vaginal option, for moderate to severe dyspareunia, a symptom of VVA, DARE-VVA1's potential to be a treatment option for the HR+ breast cancer population, the potential for the IND clearance of DARE-VVA1 to support Daré's strategic discussions, Daré's Phase 2 clinical development plans for DARE-VVA1, and the potential market opportunity for DARE-VVA1, if approved. 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 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 the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré'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 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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