Daré Bioscience Announces Publication of Positive Safety and Acceptability Data from Phase 1 Clinical Trial that Support the Potential of DARE-HRT1 Intravaginal Ring as a New Menopausal Hormone Therapy

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Daré Plans to Advance DARE-HRT1 into Single Phase 3 Efficacy Trial for Treatment of Vasomotor Symptoms due to Menopause

DARE-HRT1 has the potential to be the first FDA-approved monthly intravaginal ring delivering both estrogen and progestogen hormone therapy

SAN DIEGO, April 18, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced that *Climacteric*, the official journal of the International Menopause Society, published safety and acceptability results from a Phase 1 clinical trial of DARE-HRT1, an investigational ethylene vinyl acetate copolymer intravaginal ring (IVR) designed to release bio-identical 17β-estradiol (E2) and progesterone (P4) over 28 days. DARE-HRT1 is being developed for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause in women with intact uteri.

Hormone therapy is used to treat VMS and genitourinary syndrome associated with menopause. DARE-HRT1 has the potential to be the first FDA-approved product to offer vaginal delivery of combination bio-identical estradiol and bio-identical progesterone hormone therapy in a convenient monthly format. The North American Menopause Society's (NAMS) guidance on hormone therapy states that dosing estrogen and progestogen in combination may offer important benefits to women, and NAMS observed that non-oral routes of administration may offer advantages over orally administered therapies.

"We are very encouraged by these data which indicate that our candidate, DARE-HRT1, was well-tolerated and highly acceptable for the majority of women in both IVR treatment groups," said David Friend, PhD, Chief Scientific Officer for Daré Bioscience. "Sharing these data from our Phase 1 trial, in a recognized peer-reviewed journal, allows us to highlight the scientific rigor of our development process and showcase our innovative IVR drug delivery technology platform."

Approximately 30 healthy, postmenopausal women participated in the open-label, three-arm Phase 1 study. Women in first arm received one DARE-HTR1 ring for 28 days designed to release E2 at a rate of 80 µg/day and P4 at 4 mg/day, and women in the second arm received an alternative DARE-HRT1 ring for 28 days designed to release E2 at 160 µg/day and P4 at 8mg/day. The third arm received both oral Estrofem® (1mg E2) and Prometrium® (100 mg P4) daily for 29 days. The primary objective of the study was to assess the pharmacokinetics from the two dosage strengths of the DARE-HRT1 IVRs. The secondary objective of the study was to assess the safety of the IVRs while the exploratory objectives were to assess usability and participant tolerability of the IVRs.

The study demonstrated that the DARE-HRT1 IVRs, in general, were safe and well tolerated in healthy postmenopausal women and treatment emergent adverse events profiles were comparable between the DARE-HRT1 groups and the reference oral regimen group.

"The IVR technology used in DARE-HRT1 was developed by Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "This innovative drug delivery technology is designed to release one or more active ingredients without the need for a membrane or reservoir to contain the active drug(s) or to control the release, allowing for sustained drug delivery. We believe this IVR drug delivery technology platform has the potential to result in products that offer women a number of benefits as compared to currently marketed products, including the opportunity to improve medication compliance, avoid first-pass metabolic side effects and deliver a better overall user experience."

Previously reported topline efficacy data from a Phase 1 / 2 study of DARE-HRT1 demonstrated improvement in both VMS as well as vaginal symptoms of menopause. Following clinical development, Daré intends to leverage the existing safety and efficacy data on the active ingredients in DARE-HRT1, estradiol and progesterone, to utilize the U.S. Food and Drug Administration's (FDA) 505(b)(2) pathway to obtain marketing approval of DARE-HRT1 in the U.S.

About Menopause

Menopause is defined as the final menstrual period and is typically confirmed after a woman has missed her period for 12 consecutive months. Most women experience menopause between ages 40 and 58.[1] Over 45 million women in the U.S. are estimated to be approaching or in menopause, which results in a decrease in estrogen and other hormones.[1,2] Hot flashes, vaginal dryness and loss of bone density are frequently associated with menopause. Night sweats (hot flashes that occur during sleep) often cause sleep disturbance, and vaginal atrophy (the drying and thinning of vaginal tissues) can cause a feeling of vaginal tightness during sex along with pain, burning, or soreness.[1] Hence, management of menopausal symptoms can impact quality of life, productivity and health. The North American Menopause Society (NAMS) believes that hormone therapy is the most effective treatment for VMS and the genitourinary syndrome of menopause and observes that a non-oral route may offer potential advantages over oral routes of administration.[2]

1. Menopause 101: A primer for the perimenopausal. NAMS, accessed 4 April 2023. http://www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal.
2. NAMS Position Statement. The 2022 hormone therapy position statement of The North American Menopause Society. Menopause: The Journal of The North American Menopause Society Vol. 29, No. 7, pp. 767-794 DOI:

10.1097/GME.0000000000002028. https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf

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-HRT1's potential as a safe and effective hormone therapy for symptoms of menopause, DARE-HRT1's potential to be the first FDA-approved monthly IVR product delivering both estrogen and progestogen hormone therapy for symptoms of menopause, the importance of the results of the Phase 1 and Phase 1 / 2 clinical studies to Daré and DARE-HRT1, the anticipated regulatory approval pathway for DARE-HRT1, the potential for FDA approval of DARE-HRT1 based on a single Phase 3 clinical trial, and the potential benefits of treatment with a Daré's IVR product, if approved, compared with currently marketed products for the same indication. 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 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 must be significantly greater than anticipated; 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 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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