Daré Bioscience Announces Publication in Menopause: The Journal of The North American Menopause Society of Data from Phase 1/2 Open-Label Safety and Pharmacokinetics Study of DARE-HRT1 in Healthy Postmenopausal Women

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Daré Plans to Advance DARE-HRT1 into Single Phase 3 Efficacy Trial for Treatment of Vasomotor Symptoms (VMS) 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, June 21, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the publication in *Menopause: The Journal of The North American Menopause Society* of data from a Phase 1/2 clinical trial that evaluated the safety and pharmacokinetics of DARE-HRT1. DARE-HRT1, an investigational intravaginal ring (IVR) designed to release bio-identical 17β2-estradiol (E2) and bio-identical progesterone (P4) continuously over a 28-day period as part of a hormone therapy regimen, is part of Daré's proprietary IVR technology platform originally developed by Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School.

The article, titled "A phase 1/2, open-label, parallel group study to evaluate the safety and pharmacokinetics of DARE-HRT1 (80 µg estradiol/4 mg progesterone and 160 µg estradiol/8 mg progesterone intravaginal rings) over 12 weeks in healthy postmenopausal women," is available online through both the Latest Articles section of the *Menopause* journal's website, as well as the Scientific & Clinical Publications section of Daré's website, and will be published in Volume 30, Issue 8 of *Menopause*.

The study enrolled a total of 21 subjects, who were randomized (1:1) to receive one of two versions of DARE-HRT1, either IVR1 (E2 80 µg/d with P4 4 mg/d) or IVR2 (E2 160 µg/d with P4 8 mg/d), and used DARE-HRT1 over 12 weeks (three 28-day cycles). The study results demonstrated both versions of DARE-HRT1 were safe and released E2 in systemic concentrations in the low, normal premenopausal range and P4 in systemic concentrations predictive of endometrial protection. Data from the study support continued clinical development of DARE-HRT1 for the treatment of menopausal symptoms.

Daré previously reported positive topline data from the Phase 1/2 study of DARE-HRT1 in January 2023 and October 2022.

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 therapy in a convenient monthly format. Daré plans to advance DARE-HRT1 into a single Phase 3 clinical trial to support a new drug application for DARE-HRT1 for the treatment of moderate to severe VMS due to menopause in women with intact uteri.

"The clinical and quality of life issues associated with menopause continue to take center stage as women and healthcare providers increasingly appreciate the need for more treatment options. We are excited to have the results of our Phase 1/2 study published in this prestigious peer-reviewed journal and we believe the study results underscore DARE-HRT1's compelling therapeutic value proposition and its potential to be a first-in-category non-oral and convenient non-daily option for women suffering from vasomotor symptoms associated with menopause, such as hot flashes and night sweats," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Guidance from the North American Menopause Socierty asserts that hormone therapy remains the most effective treatment for vasomotor symptoms. Non-oral hormone therapy, including transdermal and vaginal routes of administration, may offer potential advantages compared with oral hormone therapy because non-oral routes bypass the first-pass hepatic effect. We look forward to continuing our preparation for the planned Phase 3 study and to providing updates on our progress."

DARE-HRT1 505(b)(2) Regulatory Pathway

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.

Daré intends to seek FDA approval of DARE-HRT1 for the treatment of moderate to severe VMS due to menopause in women with intact uteri. Based on pre-IND communications with the FDA and the topline PK data from the DARE-HRT1 Phase 1 / 2 study, Daré believes FDA approval of DARE-HRT1 for that indication is achievable via the 505(b)(2) pathway supported by a single, placebo-controlled, Phase 3 clinical trial of DARE-HRT1 and a scientifically justified PK "bridge" (via a relative bioavailability trial) between DARE-HRT1 and the selected listed estradiol and progesterone drugs. Ongoing activities to support progressing directly into a single Phase 3 study to support registration include manufacturing and non-clinical studies to support the IND submission and the planned IND-opening Phase 3 study.

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] An estimated 45 million women in the U.S. are 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 because non-oral routes bypass the first-pass hepatic effect.[2]

1. Menopause 101: A primer for the perimenopausal. NAMS, accessed 17 June 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 / 2 clinical study to Daré and DARE-HRT1, the anticipated regulatory approval pathway for DARE-HRT1, and the potential for FDA approval of DARE-HRT1 for the treatment of moderate to severe VMS due to menopause in women with intact uteri based on a single Phase 3 clinical trial together with study data that establishes a scientific bridge to the selected listed drugs. 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: 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; 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; 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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