



DARÉ BIOSCIENCE.

Daré Bioscience Announces Publication in The Journal of The North American Menopause Society of Positive Efficacy Findings for the Treatment of Menopausal Symptoms from a Phase 1/2 Clinical Trial of DARE-HRT1 Intravaginal Rings

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- *DARE-HRT1 Demonstrated Preliminary Treatment Efficacy for Both Vasomotor Symptoms (VMS) and Genitourinary Syndrome of Menopause (GSM)*
- *The North American Menopause Society (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*
- *Daré Plans to Advance DARE-HRT1 into Single Phase 3 Efficacy Trial for Treatment of 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, Aug. 09, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the publication of positive preliminary efficacy results from its Phase 1/2 clinical study of DARE-HRT1 in healthy postmenopausal women. DARE-HRT1, an investigational ethylene vinyl acetate copolymer intravaginal ring (IVR) designed to release bio-identical 17 β 2-estradiol and progesterone over 28 days 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. DARE-HRT1 is being developed for the treatment of moderate-to-severe VMS due to menopause in women with intact uteri.

The journal article, titled "A phase 1/2, open-label, parallel group study to evaluate the preliminary efficacy and usability of DARE-HRT1 (80 μ g estradiol/4 mg progesterone and 160 μ g 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 9 of *Menopause*. The article reports the results of the exploratory objectives of the Phase 1/2 study, which included assessing the usability, acceptability and preliminary efficacy of two dose configurations of DARE-HRT1. The results of the primary objectives of the study, which were to evaluate the safety and pharmacokinetics (PK) of the two dose configurations of DARE-HRT1, are described in a [separate article](#) published in an earlier issue of *Menopause*.

"More women are looking for options to manage their moderate-to-severe vasomotor symptoms that are commonly associated with menopause. We are encouraged by the findings from this study as we believe DARE-HRT1 has the ability to address a persistent unmet medical need," said Andrea Thurman, MD, Medical Director for Daré Bioscience and lead author of the journal article. "In this study, preliminary VMS treatment efficacy was supported by significant decreases from baseline in all domains of the Menopause-Specific Quality of Life (MENQOL) questionnaire for both dosing groups ($p < 0.01$), indicating improvement in the overall MENQOL score and in all MENQOL domains, and preliminary local GSM treatment efficacy was supported by significant improvement in vaginal cytology parameters for both dosing groups and improvement in bothersome vaginal symptoms commonly associated with GSM."

"Data from this study support further development of DARE-HRT1 as a potential first-in-category product to offer bio-identical estradiol and bio-identical progesterone therapy in a convenient monthly, non-oral format, consistent with NAMS guidance for delivering both hormones, together," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We look forward to advancing DARE-HRT1 into a single Phase 3 pivotal clinical trial to support a new drug application for the treatment of moderate-to-severe VMS due to menopause in women with intact uteri."

Hormone therapy is recommended as a first-line, effective treatment for the management of VMS and GSM among healthy postmenopausal women by the American College of Obstetricians and Gynecologists, the International Menopause Society, and NAMS. NAMS' guidance on hormone therapy states that dosing estrogen and progestogen in combination may offer important benefits to women with an intact uterus, and NAMS observed that non-oral routes of administration may offer advantages over orally administered therapies because nonoral routes bypass the first-pass hepatic effect.

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. NAMS believes that hormone therapy is the most effective treatment for VMS and GSM 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 27 July 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>

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 Investigational New Drug Application (IND) submission and the planned IND-opening Phase 3 study.

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 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, 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, and the potential market opportunity for DARE-HRT1. 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; 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; 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 loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, and public health emergencies on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including their potential impact 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 / Julia Weilman
Burns McClellan
lroth@burnsmc.com / jweilman@burnsmc.com
646.930.4406 / 646.732.4443

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Evoke Canale
jake.robison@evokegroup.com
619.849.5383

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