Daré Bioscience Initiates Phase 1/2 Clinical Study of DARE-HRT1

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Prior Phase 1 Study Results Support Potential as the First Monthly Therapy for both the Vasomotor and the Vaginal Symptoms of Menopause

Current Phase 1/2 Study will Collect Symptom Relief and Acceptability Data in Addition to Evaluating Pharmacokinetics over a Three-Month Period

SAN DIEGO, April 12, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced the initiation of a Phase 1/2 clinical study of DARE-HRT1.

DARE-HRT1 is a novel intravaginal ring (IVR) designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period as part of a hormone therapy (HT) regimen to treat the vasomotor symptoms (VMS) and genitourinary syndrome associated with menopause. Topline data reported in 2021 from a Phase 1 study evaluating pharmacokinetics (PK) of two different dose versions of DARE-HRT1 over 28 days support DARE-HRT1's 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 to treat both VMS as well as vaginal symptoms of menopause.

The open-label Phase 1/2 study that has been initiated will evaluate the PK of the same two dose versions of DARE-HRT1 (estradiol 80 µg/progesterone 4 mg IVR and estradiol 160 µg/progesterone 8 mg IVR) in approximately 20 healthy, post-menopausal women over approximately three consecutive months of use. The study will also collect safety, usability, acceptability and symptom-relief data. The study is being conducted by the company's wholly owned subsidiary in Australia.

"For some women, hormone therapy is a highly effective treatment for the symptoms associated with menopause, such as hot flashes and vaginal dryness, and may also prevent bone loss and fracture," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The delivery of hormone therapy over 28 consecutive days with no daily intervention supports DARE-HRT1's potential to be a first-in-category option offering ease-of-use and consistent dosing to women suffering from menopausal symptoms. There are currently no FDA-approved products that continuously deliver hormone therapy with both estradiol and progesterone together over multiple consecutive weeks."

The North American Menopause Society's guidance on hormone therapy includes 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.

About DARE-HRT1

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. Unlike other vaginal ring technologies, Daré's IVR drug delivery technology is designed to release more than one active ingredient via a solid ethylene vinyl acetate polymer matrix without the need for a membrane or reservoir to contain the active drug or to control the release, allowing for sustained drug delivery.
Baseline-corrected steady state release level data from the prior Phase 1 study demonstrate that both dose versions of DARE-HRT1 successfully delivered two different bio-identical hormones over the 28-day evaluation period.

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 FDA's 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.[3] An estimated 45 million women in the U.S. are approaching or in menopause, which results in a decrease in estrogen and other hormones.[1,3] 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.[3] 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 advantages over oral routes of administration.[1]

1. The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2017 Jul;24(7):728-753. DOI: 10.1097/GME.0000000000000921
2. Kuhl, H. (2005) Pharmacology of estrogens and progestogens: influence of different routes of administration. *Climacteric,* 8:sup1, 3–63. DOI: 10.1080/13697130500148875
3. Menopause 101: A primer for the perimenopausal. NAMS, accessed 11 April 2022. http://www.menopause.org/for-women/menopauseflashes/menopause-symptoms-and-treatments/menopause-101-a-primer-for-the-perimenopausal.

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, fertility, and vaginal and sexual health.

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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. The Company's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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 hormone therapy following menopause. 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 monthly therapy for VMS and vaginal symptoms of menopause, the potential of Daré's IVR technology to provide a platform for development of other vaginally delivered therapies, and the anticipated regulatory approval pathway 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, risk and uncertainties related to: 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 clinical trial material, and if any of its product candidates are approved, to manufacture commercial product; 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 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 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 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 developments by competitors make Daré's product or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product candidates, if approved; 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, product candidates or business activities; 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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