Daré Bioscience Announces Initiation of Phase 1 Clinical Trial of DARE-HRT1, a Novel Intravaginal Ring Designed to Deliver Non-oral, Bio-identical Hormone Therapy for the Treatment of Menopausal Symptoms

July 27, 2020

More than 45 million women in the U.S. are approaching or in menopause

SAN DIEGO, July 27, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the initiation of a Phase 1 clinical trial of DARE-HRT1.

DARE-HRT1 is designed to deliver bio-identical 17β-estradiol and bio-identical progesterone continuously over a 28-day period and is being developed as a potential new option for hormone therapy (HT) for the treatment of vasomotor symptoms, commonly called hot-flashes, and the genitourinary syndrome of menopause to prevent bone loss and fracture associated with menopause. The North American Menopause Society (NAMS) hormone therapy position statement supports the use of HT in peri- and post-menopausal women, recommends administering both estrogen to reduce symptoms and progesterone to prevent thickening of the uterine wall and observes that non-oral routes of administration may offer advantages over orally administered therapies.[1] DARE-HRT1 has the potential to be the first FDA-approved intravaginal ring (IVR) product to meet these NAMS guidelines.

"We believe this study will provide important scientific information for both DARE-HRT1 and DARE-FRT1, two of our development-stage programs, given that they both utilize the same IVR technology and bio-identical progesterone as an active ingredient," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "Specifically, this Phase 1 study of DARE-HRT1 will evaluate the ability of DARE-HRT1 to achieve its target dual release objectives, as well as the ability of the IVR technology to release two different active drugs at two different rates. In addition, we anticipate collecting useful pharmacokinetics characteristics of the bio-identical progesterone alone, which can be expected to directly apply to DARE-FRT1, a bio-identical progesterone-only IVR being developed for luteal phase support as part of an invitro fertilization regimen and as a more convenient treatment option for prevention of pre-term birth."

The randomized Phase 1 study will evaluate the pharmacokinetics (PK) of DARE-HRT1 in approximately 30 healthy, post-menopausal women. The primary objective of the study is to describe the PK parameters over 28 days of two different dose combinations of DARE-HRT1. Secondary endpoints of the study include assessing the safety and tolerability of DARE-HRT1 and comparing the exposure of estradiol, estrone, and progesterone of DARE-HRT1 over 28 days against a daily combination of oral estrogen (Estrofem®) and oral progesterone (Prometrium®).

The Phase 1 study of DARE-HRT1 is being conducted by Daré's wholly-owned Australian subsidiary at specialty women's health sites in Australia. Currently, Australia's research and development tax incentive (R&DTI) gives 43.5% of every dollar spent by eligible companies on eligible R&D activities back to those companies in a cash payment. At the conclusion of the Phase 1 study, Daré's subsidiary intends to apply for the maximum refundable cash credit then available under the Australian R&DTI program for eligible study costs incurred.

"At Daré, we have a deep passion and commitment for transforming science into solutions for women," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "The polymer-based segmented IVR delivery platform developed by renowned scientists Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School is a truly innovative technology designed specifically for women to avoid first-pass metabolic effects commonly seen with oral medications and to offer potentially more convenient approaches for sustained delivery of one or more active drugs at variable doses and convenient durations, including a once-a-month option. The potential cost savings afforded by the Australian R&D tax incentive program provides an opportunity to advance potential first-in-category product candidates like DARE-HRT1 and DARE-FRT1 capital efficiently."

1. *Menopause: The Journal of The North American Menopause Society*, Vol. 24, No. 7, pp. 728-53 (2017)

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's clinical-stage product candidates include potential first-in-category candidates in clinical development: Ovaprene®, a hormone-free, monthly contraceptive intravaginal ring 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®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré's full portfolio of women's health product candidates, and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations 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 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 on its investor relations website (https://darebioscience.gcs-web.com/) 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 on the investor relations page of Daré's website mentioned above.

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," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, the potential for DARE-HRT1 to safely and effectively treat menopausal symptoms, the potential for DARE-HRT1 to be the first FDA-approved IVR to deliver bio-identical progesterone in combination with bio-identical estradiol; the utility of the Phase 1 clinical study of DARE-HRT1 in the development of DARE-FRT1, and the potential to receive a significant refundable tax credit under Australia's R&D tax incentive program for eligible costs incurred in the conduct of the Phase 1 clinical study of 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 raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic 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, including its clinical trials, to fulfill their contractual obligations to Daré; Daré's ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining U.S. Food and Drug Administration (FDA) or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to conduct and design 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; 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 retain its licensed rights to develop and commercialize a 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 candidates; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; 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.

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth
Burns McClellan
Email: lroth@burnsmc.com
+1 212-213-0006

Source: Daré Bioscience, Inc.