Daré Bioscience Completes Recruitment in Phase 1 Clinical Trial of DARE-HRT1, a Novel Intravaginal Ring Designed to Deliver Non-Oral, Bio-identical Hormone Therapy for the Treatment of Vasomotor Symptoms & Genitourinary Syndrome Associated with Menopause

March 22, 2021

Topline data readout anticipated in the second quarter 2021

SAN DIEGO, March 22, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced completion of patient recruitment in its Phase 1 clinical trial of DARE-HRT1 being conducted through its wholly owned subsidiary in Australia.

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. It is being developed for the treatment of vasomotor symptoms (VMS) and genitourinary syndrome associated with menopause as part of a hormone therapy regimen.

The randomized Phase 1 study is designed to 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 of two different dose combinations over 28 days. 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 IVR drug delivery technology used in DARE-HRT1 is an important platform for Daré as we believe it offers a versatile drug delivery system in women's health with the potential to improve convenience and outcomes," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "The objective of this Phase 1 study of DARE-HRT1 is to evaluate the ability of DARE-HRT1 to achieve its dual release objectives, as well as the ability of the IVR technology to release two different active drugs at two different rates."

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.

Hormone therapy is considered the most effective treatment for vasomotor symptoms, commonly referred to as hot flashes, and the genitourinary syndrome of menopause, and has been shown to prevent bone loss and fracture. There are currently no FDA-approved IVRs that deliver bio-identical progesterone in combination with bio-identical estradiol. As such, DARE-HRT1 has the potential to be a first-in-category product that offers monthly convenience for women. 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.

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. Daré's subsidiary has and intends to continue to apply for the maximum refundable cash credit available under the Australian R&DTI program for eligible study costs incurred.

Daré anticipates reporting topline data from this study in the second quarter of 2021.

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 product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal contraceptive candidate 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 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 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 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 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. In this press release, forward-looking statements include, but are not limited to, statements regarding the timing of topline data from the Phase 1 clinical trial of DARE-HRT1, the potential for Daré’s IVR technology to provide for safe and effective sustained release of one or more active ingredients in human subjects, and the potential therapeutic application of the IVR drug delivery technology in women’s health. 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 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 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; the risk that developments by competitors make Daré’s product candidates less competitive or obsolete; failure of Daré’s product candidates, if approved, to gain market acceptance or obtain adequate coverage from third party payers; 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; 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.

Contact:

Investors on behalf of Daré Bioscience, Inc.:

Tom Masterson
Allele Capital Partners
tmasterson@allelecapital.com
646.573.3216

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.