Daré Bioscience Announces Publication of Pharmacokinetics Study of DARE-HRT1, a Potential Hormone Replacement Therapy, in the Journal of Pharmaceutical Sciences

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SAN DIEGO, April 08, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the article entitled "Pharmacokinetics and tolerability of a novel 17β-estradiol and progesterone intravaginal ring in sheep" was published online in the *Journal of Pharmaceutical Sciences* (JPharmSci®). The goal of the research described in the article was to characterize the release, pharmacokinetics and local tolerability of DARE-HRT1, a potential and novel hormone replacement therapy. DARE-HRT1, an ethylene-vinyl acetate (EVA) intravaginal ring (IVR) drug delivery technology delivering 17β-estradiol (E2) and progesterone (P), was evaluated in drug-naïve ovariectomized female Dorset crossbred sheep.

DARE-HRT1 is being developed as a combination bio-identical estradiol and bio-identical progesterone IVR for hormone replacement therapy (HRT) to treat vasomotor symptoms (VMS), commonly called hot-flashes and associated with menopause, as part of an HRT regimen. The North American Menopause Society (NAMS) consensus statement supports HRT in peri- and post-menopausal women and recommends administering both estrogen to reduce symptoms and progesterone to prevent thickening of the uterine wall, in addition to recommending a non-oral route over an oral route.[1] The design of DARE-HRT1 is intended to allow the continuous delivery of bio-identical estradiol and bio-identical progesterone in one IVR over a 28- day period.

"We believe achieving predictable and sustained release rates of bio-identical hormones in a large animal model, as published in JPharmSci, is a validation of the viability of our IVR technology platform," said Dr. David Friend, co-author of the article and Chief Scientific Officer for Daré Bioscience. "We believe the results of this study are highly encouraging. The IVRs were well tolerated and we saw no abnormal findings in any of the groups."

In a separate study of 44 healthy female post-menopausal women, more than 90 percent said an IVR would make taking their medications easier and 88 percent reported they would be very likely to use an IVR for a condition related to Women's Health. [2]

"With more than 45 million women approaching menopause in the United States, the demand for new innovation to treat HRT is accelerating at a rapid pace," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We are highly encouraged by these findings and plan to advance our DARE-HRT1 program into a human clinical study this year. In addition, we expect to advance our novel IVR-based fertility program, DARE-FRT1, into a human clinical study in approximately 12 to 18 months."

For full access to the JPharmSci article, please visit https://jpharmsci.org/. For more information on Daré, please visit www.darebioscience.com.

1. Menopause, Vol. 19, No. 3, 2012.
2. Leonard-Segal, Acceptability and Tolerability of an Intravaginal Ring in Postmenopausal Women, Accepted for North American Menopause Society, Philadelphia, PA, 11 October 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 product portfolio includes potential first-in-class candidates in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive intravaginal ring; 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 the company'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, statements relating to plans to advance DARE-HRT1 into a human clinical study this year and to advance DARE-FRT1 into a human clinical study in approximately 12 to 18 months. 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; 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; 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.

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