Daré Bioscience Announces the Publication of a Pharmacokinetics Study of DARE-FRT1, a Potential Therapy for Preterm Birth and Fertility, in Drug Delivery and Translational Research

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SAN DIEGO, May 8, 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 progesterone intravaginal ring in sheep" was published online in the journal *Drug Delivery and Translational Research*. The goal of the research was to characterize the in vitro release, pharmacokinetics and local tolerability of DARE-FRT1, a novel ethylene-vinyl acetate intravaginal ring (IVR) drug delivery technology delivering progesterone, in drug-naïve ovariectomized female Dorset crossbred sheep.

DARE-FRT1 is being developed as an optimized IVR technology capable of delivering bio-identical progesterone hormone for the prevention of preterm birth (PTB), and for pregnancy maintenance and support as part of an assistive reproductive technology (ART) procedure. DARE-FRT1 is designed to allow for convenient non-invasive, non-oral administration of bio-identical progesterone over a 14-day period.

"We believe the results of this study are highly encouraging as they further validate the viability of the IVR technology platform for drug delivery," said David Friend, PhD, co-author of the article and Chief Scientific Officer of Daré Bioscience. "As with our previously reported study of DARE-HRT1, DARE-FRT1 was well tolerated and we look forward to continuing its development into the clinic as a potential first-in-category therapy for preterm birth and fertility."

The March of Dimes, an organization dedicated to the health and wellbeing of mothers and infants, supports the use of progesterone to reduce the risk of PTB, defined as birth before 37 weeks of completed gestation[1], and the Society for Assisted Reproductive Technology supports the use of progesterone after egg retrieval to support the lining of the uterus.[2] According to the Centers for Disease Control and Prevention (CDC), about 10% of women in the U.S. between the ages of 15-44, or 6.1 million women, face difficulty in getting or staying pregnant.[3] AMAG Pharmaceuticals, the maker of Makena®, the first and, until 2018, only product approved by the U.S. Food and Drug Administration (FDA) to reduce the risk of PTB, reported 2018 annual revenue in excess of $320 million for Makena and its authorized generic[4] and, according to the research firm Global Market Insights, the global ART market will surpass $32.5 billion by 2024.[5]

"With approximately 10% of all pregnancies in the United States resulting in preterm births,[6] and the increasing demand for pregnancy support as part of ART procedures, DARE-FRT1 could address significant unmet needs in women's health. DARE-FRT1 has the potential to be the first and only FDA-approved product capable of delivering bio-identical progesterone in a convenient, non-systemic and non-invasive way over a period of several days," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience.

For more information, access to the scientific paper entitled "Pharmacokinetics and tolerability of a novel progesterone intravaginal ring in sheep" is available at https://link.springer.com/article/10.1007/s13346-019-00646-x

1 – March of Dimes website, https://www.marchofdimes.org/complications/progesterone-treatment-to-help-prevent-premature-birth.aspx

2 – Society for Assisted Reproductive Technology website, https://www.sart.org/patients/a-patients-guide-to-assisted-reproductive-technology/stimulation/progesterone/

3 – U.S. Department of Health and Human Services Office on Women's Health website,

https://www.womenshealth.gov/a-z-topics/infertility

4 - AMAG Pharmaceuticals, Inc. press release dated February 7, 2019, https://www.globenewswire.com/news-release/2019/02/07/1712029/0/en/AMAG-Reports-Fourth-Quarter-and-Full-Year-2018-Financial-Results-and-Provides-Company-Update.html

5 - Global Market Insights, Inc. press release dated January 23, 2019, https://www.prnewswire.com/news-releases/assisted-reproductive-technology-market-to-hit-32-5-billion-by-2024-global-market-insights-inc--843521697.html

6 - Martin J, et al., Births: final data for 2017, *National Vital Statistics Reports*, Vol. 67, No. 8, Nov 7, 2018, https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_08-508.pdf[1]

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.

This press release includes information obtained from, and makes reference to, trade and statistical services and other third-party publications and sources. Daré has not independently verified such information and, although the company is not aware of inaccuracies in such third-party information, there can be no assurance as to its accuracy.

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-FRT1 into a human clinical study and DARE-FRT1's potential to obtain FDA approval for the prevention of preterm birth and/or pregnancy maintenance and support as part of an ART procedure and to be a first-in-category product. 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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