Daré Bioscience Announces the Publication of a Pharmacokinetics Study of DARE-VVA1, a Novel Application of Tamoxifen for the Treatment of Vulvar and Vaginal Atrophy, in the International Journal of Pharmaceutics

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SAN DIEGO, Sept. 11, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the article entitled "Vaginal tamoxifen for treatment of vulvar and vaginal atrophy: Pharmacokinetics and local tolerance in a rabbit model over 28 days" was published online in the *International Journal of Pharmaceutics*.

The article highlights the positive findings from the animal study which include availability and local tolerability of vaginally delivered tamoxifen. DARE-VVA1 is a novel vaginal application of tamoxifen, the well-known and well-characterized selective estrogen receptor modulator (SERM), and is being developed by Daré as an alternative to estrogen-based therapies for the treatment of vulvar and vaginal atrophy (VVA) in women with or at risk for hormone-receptor positive (HR+) breast cancer. In breast tissue, tamoxifen acts as an estrogen antagonist, while in other tissue, including vaginal tissue, tamoxifen has been reported to exert an estrogen-like response on vaginal cytology.

The goal of the study was to evaluate tamoxifen at two dose levels (1 mg or 20 mg) administered intra-vaginally to female rabbits once-daily over a 28-day period to assess its pharmacokinetics, systemic exposure and local vaginal tolerance. The findings revealed that there was little to no vaginal or systemic accumulation of tamoxifen following once-daily dosing for 28 days and that vaginal irritation was minimal to none at both doses.

"We are highly encouraged by these findings as tamoxifen was minimally metabolized at both doses with essentially no detectable vaginal irritation evident over the course of the study," said David Friend, PhD, co-author of the article and Chief Scientific Officer of Daré Bioscience.

VVA is an inflammation of the vaginal epithelium due to the reduction in levels of circulating estrogen. Commonly used therapies for VVA are estrogen-based and often contraindicated in HR+ breast cancer patients, or patients with a genetic predisposition or history of familial disease, because of the concern that estrogen use will promote recurrence of disease.[1] Many breast cancer survivors experience menopausal symptoms as a direct consequence of cancer treatment. Breast cancer patients treated with aromatase inhibitors refer to VVA as one of the most unpleasant side effects of treatment.[2] A prior study of DARE-VVA1 published in *Clinical and Experimental Obstetrics and Gynecology*, demonstrated that weekly vaginal administration of tamoxifen for three months in post-menopausal women with VVA showed improvements in vaginal pH and vaginal dryness without significant systemic absorption of tamoxifen.[3]

The abstract of the scientific paper entitled "Vaginal tamoxifen for treatment of vulvar and vaginal atrophy: Pharmacokinetics and local tolerance in a rabbit model over 28 days" is available at https://doi.org/10.1016/j.ijpharm.2019.118691

1. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Use-of-Vaginal-Estrogen-in-Women-With-a-History-of-Estrogen-Dependent-Breast-Cancer?IsMobileSet=false
2. Biglia N., Bounous V.E., D'Alonzo M., Ottino L., Tuninetti V., et al.: "Vaginal Atrophy in Breast Cancer Survivors: Attitude and Approaches Among Oncologists". Clin. Breast Cancer, 2017, 17, 611.
3. Clin. Exp. Obstet. Gynecol. - XLVI, n. 2, 2019 (doi: 10.12891/ceog4948.2019)

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 hormone-free, 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 uses these channels to communicate with its investors and the public about the company and other company-related matters. The information Daré posts on its investor relations website 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: www.darebioscience.com.

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 DARE-VVA1's potential to treat VVA. 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; the risk that promising results in pre-clinical studies may not be replicated when a product candidate is tested in human subjects; 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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