Daré Bioscience Announces 2019 AAPS Best Abstract Award for Vaginal Tamoxifen for Treatment of Vulvovaginal Atrophy: Pharmacokinetics and Safety in a Rabbit Model

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DARE-VVA1 is a proprietary formulation of tamoxifen for vaginal administration as a potential treatment for VVA in patients with hormone receptor-positive breast cancer

SAN DIEGO, July 17, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that it has received notification from the American Association of Pharmaceutical Scientists (AAPS) of a Best Abstract Award for the abstract titled, *Vaginal Tamoxifen for Treatment of Vulvovaginal Atrophy: Pharmacokinetics and Safety in a Rabbit Model*. The abstract was among the top 10% of abstracts highly ranked by AAPS Abstract Screeners.

The abstract presented topline findings from a pharmacokinetic and local tolerability study of vaginal tamoxifen in female rabbits. Daré's product candidate, DARE-VVA1, incorporates tamoxifen in a proprietary formulation designed for vaginal delivery.

Daré is investigating the use of tamoxifen, a commonly prescribed treatment for breast cancer, as a new way of addressing vulvar and vaginal atrophy (VVA) for women unable or unwilling to use hormone-based therapies to treat their condition. VVA is an inflammation of the vaginal epithelium due to the reduction in levels of circulating estrogen. Historically, estrogen creams, rings, and tablet supplements have been prescribed for the treatment of VVA. These products, however, can be contraindicated for women undergoing treatment for hormone receptor-positive breast cancer.[1]

"This work is fundamental to the further development of a vaginally delivered tamoxifen for the treatment of symptoms associated with VVA in hormone receptor-positive breast cancer patients," said Dr. David Friend, Chief Scientific Officer of Daré Bioscience. "These results are highly encouraging and support the further development of vaginally delivered tamoxifen for the treatment of VVA."

Many breast cancer survivors experience menopausal symptoms, including VVA, as a direct consequence of their anti-cancer treatment with aromatase inhibitors. Breast cancer patients treated with aromatase inhibitors refer to VVA as one of the most unpleasant side effects of treatment.[2]

"If successful, vaginally delivered tamoxifen will address a critical unmet need for women diagnosed with hormone receptor-positive breast cancer experiencing the effects of VVA as a result of their anti-cancer therapy," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "Consistent with our portfolio of first-in-category opportunities, we believe this novel application of tamoxifen has the potential to be the first therapy that will specifically address VVA in the hormone receptor-positive breast cancer market segment."

Tamoxifen is systemically metabolized to active metabolite 4-hydroxy-N-desmethyl-tamoxifen, otherwise known as endoxifen.[3] In breast tissue, tamoxifen acts as an estrogen antagonist. In other tissue, including vaginal tissue, tamoxifen has been reported to exert an estrogen-like response on vaginal cytology by a mechanism yet to be understood and not expected based upon its anti-estrogen activity.

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. Etienne M.C., Milano G., Fischel J.L., Frenay M., Francois E., et al.:"Tamoxifen metabolism: pharmacokinetic and in vitro study". Br. J.Cancer, 1989, 60, 30.

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 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 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.

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 DARE-VVA1's potential to be successfully developed and approved for the treatment of VVA and to become a first-in-category therapy for hormone receptor-positive breast cancer patients with 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; 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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