Daré Bioscience Announces Publication of Positive Clinical Findings for Vaginal Administration of Tamoxifen for the Treatment of VVA

03-18-2019 at 8:00 AM EDT

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, March 18, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced the publication of clinical findings for vaginally-administered tamoxifen in *Clinical and Experimental Obstetrics and Gynecology*, a leading international journal for publication of research focused on the development of new therapeutic interventions for obstetrics and gynecology. Daré's product candidate, DARE-VVA1, incorporates tamoxifen in a proprietary formulation designed for vaginal delivery. Daré holds the exclusive worldwide rights to patents issued in the U.S. and Japan covering the use and delivery of DARE-VVA1 for vulvar and vaginal atrophy (VVA) and a U.S. patent covering composition, use and delivery of DARE-VVA1 for VVA.

The publication entitled, "Weekly vaginal administration of tamoxifen for three months in post-menopausal women with vulvar and vaginal atrophy: a possible new treatment approach?," reported that a self-administered vaginal suppository containing tamoxifen (20 mg), dosed daily for one week followed by twice weekly for three months, administered to four healthy postmenopausal women with VVA showed significant improvements in reducing vaginal pH and vaginal dryness without significant systemic absorption of tamoxifen.

This exploratory study demonstrated that tamoxifen was effective when delivered intravaginally for three months in postmenopausal women suffering with VVA. The median vaginal pH at the time of enrollment was 7.1 (range 6.5 to 7.5). At the end of month 3, the median vaginal pH was 5.0 (range 5.0 to 5.2). The median paired difference between baseline and month 3 was -2.0, with a range of -2.5 to -1.5. The self-assessment of vaginal dryness improved between baseline and month 3. Vaginal dryness was rated using a visual analogue scale (VAS) that ranged from 0 (participant was not bothered by the dryness) to 10 (participant was extremely bothered by the dryness). At baseline, the median vaginal dryness rating was 8.0, with a range of 7.5 to 9.0. At the end of month 3, the median vaginal dryness rating was 3.0, with a range of 2.0 to 3.0. The median change between baseline and month 3 was -5.5, (range -6.0- to -4.5).

In addition, systemic exposure was at least an order of magnitude lower following vaginal administration compared with oral tamoxifen. After eight weeks of study treatment, median plasma concentration of tamoxifen was 5.8 ng/ml, with a range of 1.0 to 10.0 ng/ml. In comparison, after three months of oral administration of 20-mg tamoxifen once daily, the average steady state plasma concentration of tamoxifen is 122 ng/ml, with a range of 71 to 183 ng/ml.[1]

VVA is an inflammation of the vaginal epithelium due to the reduction in levels of circulating estrogen. Historically, estrogen-based therapies delivered through creams, rings, and tablet supplements have been prescribed for the treatment of VVA symptoms. However, estrogen-based products can be worrisome for women undergoing treatment for hormone-receptor positive breast cancer and are often contraindicated in such breast cancer patients and in patients with a genetic predisposition or history of familial disease, because of the concern that estrogen use will promote recurrence of disease.[2] Many breast cancer survivors undergo 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.[3]

Tamoxifen has been a commonly used treatment for breast cancer and is systemically metabolized to active metabolite 4-hydroxy-N-desmethyl-tamoxifen, otherwise known as endoxifen.[4] 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 an anti-estrogen activity.

This exploratory study demonstrated that vaginal administration of tamoxifen for three months in postmenopausal women with VVA is a possible new, non-estrogen-based treatment approach. Daré is currently conducting activities in preparation for future clinical work with DARE-VVA1, its proprietary vaginal formulation of tamoxifen. If successful, DARE-VVA1 could be the first and only vaginally administered tamoxifen product approved by the FDA for the treatment of VVA in hormone-receptor positive breast cancer patients. According to the American Cancer Society, roughly 2 out of every 3 cases of breast cancer are hormone receptor-positive. Most of these cases are ER-positive, meaning that there are estrogen receptors on the surface of the cell that bind to estrogen.[5]

1. US Food and Drug Administration: “Drug Approval Package: Nolvadex (Tamoxifen Citrate) NDA# 21-109.2002”. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21109_Nolvadex.cfm
2. 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
3. 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.
4. 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.
5. https://www.healthline.com/health/breast-cancer/er-positive-prognosis-life-expectancy

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 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: Daré’s future clinical development of DARE-VVA1 and the potential of DARE-VVA1 to be the first and only FDA-approved vaginally delivered tamoxifen product for treatment of VVA in hormone-receptor positive breast cancer patients. 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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