Daré Bioscience Provides Update on Activities to Support Commercial Launch of XACIATO™ (clindamycin phosphate) vaginal gel, 2%, FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis

July 5, 2023

Daré to receive $1 million in July 2023 and $181.8 million in potential milestone payments from Organon under XACIATO global license agreement

SAN DIEGO, July 5, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today reaffirmed its commitment to the commercial launch of XACIATO [zah-she-AH-toe] (clindamycin phosphate) vaginal gel, 2% with collaborator Organon (NYSE: OGN), and announced that Organon will pay Daré $1.0 million in July 2023.

"We believe Organon's commercial capabilities and track record of success in the branded women's health category will help ensure a successful introduction of XACIATO in the United States and, ultimately, that XACIATO reaches the global population of women suffering from bacterial vaginosis, which is estimated to impact between 23% to 29% of all women worldwide," said Sabrina Martucci Johnson, President and CEO of Daré. "Daré has completed manufacturing validation activities required to support commercial launch. To provide for continuity of supply to support a robust commercial launch, additional manufacturing related activities are being performed and Organon and Daré are working towards a 2023 U.S. launch as soon as feasible. We are confident that XACIATO will be well positioned for commercial success given the knowledge and experience of Organon's sales team, which is the same sales team that helped drive the market acceptance and record sales of NEXPLANON®, coupled with Organon's payer outreach and provider and patient-centered initiatives, and we look forward to the launch later this year."

Under the amended license agreement between Daré and Organon for XACIATO, Organon will pay Daré $1.0 million in July 2023 and will pay Daré $1.8 million upon the first commercial sale of XACIATO. In 2022, Daré received a $10.0 million upfront payment from Organon when the license agreement became effective. In addition to the upfront payment and the $2.8 million described above, Daré is also eligible to receive additional potential future milestone payments of up to $180.0 million and tiered double-digit royalties based on net sales.

As Daré previously shared, the New Drug Application (NDA) for XACIATO was supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating XACIATO (formerly known as DARE-BV1) for the treatment of bacterial vaginosis (NCT04370548).

About XACIATO

XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older. A single-dose user-filled disposable applicator delivers 5g of vaginal gel containing 100mg of clindamycin.

Selected Safety Information

XACIATO is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile may need to be discontinued.

Polyurethane condoms are not recommended during treatment with XACIATO or for 7 days following treatment. During this time period, polyurethane condoms may not be reliable for preventing pregnancy or for protecting against transmission of HIV and other sexually transmitted diseases. Latex or polyisoprene condoms should be used.

XACIATO may result in the overgrowth of Candida spp. in the vagina resulting in vulvovaginal candidiasis, which may require antifungal treatment.

The most common adverse reactions reported in >2% of patients and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.

XACIATO has not been studied in pregnant women. However, based on the low systemic absorption of XACIATO following the intravaginal route of administration in nonpregnant women, maternal use is not likely to result in significant fetal exposure to the drug.

There are no data on the effect of clindamycin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.

Please see the Prescribing Information, Patient Information, and Instructions for Use.

About Daré Bioscience

Daré Bioscience is a biopharmaceutical company committed to advancing 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 prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, vaginal health, reproductive health, menopause, sexual health and fertility.

Daré's first FDA-approved product, XACIATO™ (clindamycin phosphate) vaginal gel, 2% is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older, which is under a global license agreement with Organon. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal contraceptive whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. To learn more about XACIATO, Daré's full portfolio of women's health product candidates, and Daré's mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product and product candidates, clinical trials and other matters using the Investors section of its 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 and 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 in the Investors section of its website 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 in the Investors section of Daré's website.

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," "objective," or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements relating to Daré's expectations about commercial distribution and sale of XACIATO, receipt of payments from Organon, and expected timing of commercial availability of XACIATO in the United States. 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 those expressed or implied by the forward-looking statements in this press release, including, without limitation: the risks that none of the milestones under the agreement with Organon may be achieved and none of potential milestone payments become payable; the potential for royalty payments to be subject to reductions and offsets; dependence on Organon to commercialize licensed products and on other third parties for commercial supplies of licensed products and components and Daré's lack of control over the efforts and resources expended by those third parties; Daré's ability to raise additional capital when and as needed to support its operations, execute its business strategy and continue as a going concern; general industry conditions and competition; the effects of macroeconomic conditions such as inflation, rising interest rates and geopolitical events on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; failure of Daré's product or product candidates, if approved, to gain market acceptance or obtain adequate coverage or reimbursement from third-party payers; Daré's ability to retain its licensed rights to develop and commercialize a product or 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 and product candidates; 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; product liability claims; governmental investigations or actions relating to Daré's product or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cyber-attacks, security breaches or similar events that compromise Daré's technology systems or those of third parties on which it relies and/or significantly disrupt Daré's business; 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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