Daré Announces FDA Approval of XACIATO™ (clindamycin phosphate) Vaginal Gel as a Treatment for Bacterial Vaginosis

December 7, 2021

- ***Prescribing information supports positioning of XACIATO as a first line option for the treatment of bacterial vaginosis***
- ***This marks the first FDA-approved product in Daré's portfolio of potential first in category development candidates***
- ***Strategic partnering discussions ongoing; Conference call will be scheduled once a definitive partnership agreement for commercialization of XACIATO in the U.S. is finalized and executed; U.S. commercial launch expected 2022***

SAN DIEGO, Dec. 07, 2021 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced that the U.S. Food and Drug Administration (FDA) approved XACIATO [zah-she-AH-toe] (clindamycin phosphate vaginal gel, 2%) (formerly known as DARE-BV1) for the treatment of bacterial vaginosis in females 12 years of age and older.

"The FDA approval of XACIATO marks a major milestone not only for Daré as a company but, importantly, for the 21 million women impacted by bacterial vaginosis," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "It is our goal as a company to accelerate the development of differentiated products that can improve outcomes and convenience for women. In the case of XACIATO, this FDA approval comes just three years after we licensed this technology. We are grateful to the FDA for their thoughtful review and the alignment on labeling that gives healthcare providers clear insights into how to use XACIATO in those patient populations in greatest need of a therapeutic option, such as pregnant women and women with recurrent episodes of bacterial vaginosis. We hope that this is the first of many FDA approvals in our efforts to improve the lives of women with treatment options that address some of the most persistent unmet needs."

"Bacterial vaginosis is not a sexually transmitted infection, but rather an overgrowth of bacteria naturally found in the vagina, which upsets the balance of the natural vaginal microbiome and leads to not only distressing symptoms of odor and discharge, but also increases a woman's risk of preterm birth, infertility, and infections. Today, approximately half of the women treated for bacterial vaginosis experience a recurrence within 12 months of treatment. There is a need for more efficacious and convenient treatment options, particularly products with improved clinical outcomes for not only the newly diagnosed women, but, importantly, also for the women who experience multiple episodes of bacterial vaginosis each year," said David Friend, Ph.D., Daré's Chief Scientific Officer. "Now that we have achieved this important demonstration of this drug delivery hydrogel platform technology, we are actively exploring the opportunity to leverage it across other unmet needs in women's health."

About Bacterial Vaginosis

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the United States.[1,2] Prevalence of bacterial vaginosis among non-white women in the U.S. is higher than among white women (African American 51%, Mexican American 32%, white 23%).[2] Bacterial vaginosis can cause serious health risks and very disruptive symptoms. While there are several therapeutic options for women in the U.S. diagnosed with bacterial vaginosis, currently approved options have relatively insufficient clinical cure rates, require sequential daily administrations or can be otherwise inconvenient for women to use. It is estimated that as many as 50% of women treated for bacterial vaginosis will experience a recurrence within 12 months of their treatment.[3]

1. Clinical Infectious Diseases 2007; 44:213–9; https://doi.org/10.1086/509577
2. Centers for Disease Control and Prevention Bacterial Vaginosis (BV) Statistics; https://www.cdc.gov/std/bv/stats.htm. Accessed December 7, 2021.
3. The Journal of Infectious Diseases 2006; 193:1478–86; https://www.ncbi.nlm.nih.gov/pubmed/16652274

About XACIATO™ (clindamycin phosphate) Vaginal Gel

XACIATO is the trade name for clindamycin phosphate vaginal gel, 2%. XACIATO is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older. XACIATO is a clear, colorless, viscous gel, which contains clindamycin at a concentration of 2% (present as clindamycin phosphate). A single-dose user-filled disposable applicator delivers 5 g of vaginal gel containing 100 mg of clindamycin. The New Drug Application (NDA) for XACIATO was approved by the FDA on December 7, 2021.

The NDA was supported by positive results from the DARE-BVFREE Phase 3 randomized, multi-center, double-blinded, placebo-controlled clinical trial evaluating XACIATO in women diagnosed with bacterial vaginosis (NCT04370548).

XACIATO received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis. As a result of the QIDP designation, XACIATO is expected to receive a five-year extension of the three years of market exclusivity available to the product based on the submission of new clinical data that were essential to its approval. Strategic partnering discussions and other activities

intended to support a robust market introduction of XACIATO in 2022 in the United States are ongoing and a conference call to discuss the partnership and market introduction strategy will be scheduled once a definitive partnership agreement is finalized and executed.

Please click here for full Prescribing Information.

Important Safety Information

Indication: XACIATO (clindamycin phosphate) vaginal gel is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older.

Dosage and Administration: Administer one applicatorful (5 g of gel containing 100 mg of clindamycin) once intravaginally as a single dose at any time of the day. Not for ophthalmic, dermal, or oral use.

Contraindications: XACIATO is contraindicated in patients with a history of hypersensitivity to clindamycin or lincomycin.

Warnings and Precautions:

- *Clostridioides difficile*-Associated Diarrhea (CDAD): Discontinue and evaluate if diarrhea occurs
- Use with Polyurethane Condoms: 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.

Adverse Reactions: The most common adverse reactions reported in >2% of patients in the Phase 3 placebo-controlled trial and at a higher rate in the XACIATO group than in the placebo group were vulvovaginal candidiasis and vulvovaginal discomfort.

Drug Interactions: Systemic clindamycin has neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. It should be used with caution in patients receiving such agents.

Use in Specific Populations:

- Other clindamycin vaginal products have been used to treat pregnant women during the second and third trimester. 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, material use is not likely to result in significant fetal exposure to the drug.
- Similarly, because systemic absorption following intravaginal administration of clindamycin is low, transfer of the drug into breastmilk is likely to be low and adverse effects on the breastfed infant are not expected.
- The safety and effectiveness of XACIATO have not been established in pediatric patients younger than 12 years of age.

To report SUSPECTED ADVERSE REACTIONS, contact Daré Bioscience at 866-XACIATO (866-922-4286) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Daré Bioscience

Daré Bioscience is a clinical-stage 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, fertility, and vaginal and sexual health.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly 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 hormone therapy following menopause. Daré's New Drug Application (NDA) for XACIATO (clindamycin phosphate) vaginal gel (formerly known as DARE-BV1) was approved by the FDA on December 7, 2021. 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 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 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 on the investor relations page of Daré's website mentioned above.

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," 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 a commercial partnership for XACIATO, the timing of commercial launch of XACIATO in the U.S., XACIATO's potential to be prescribed as a first line option for the treatment of bacterial vaginosis, and the potential for Daré's development of other women's health products utilizing the drug delivery hydrogel technology in XACIATO. 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 establish commercialization arrangements or capabilities for XACIATO on a timely basis or on acceptable terms, or at all; Daré's reliance on third parties for the commercialization of XACIATO, including manufacturing, distribution, marketing, sales and compliance capabilities; the risk that XACIATO may not be accepted by healthcare providers and patients; the risk that XACIATO will not obtain adequate coverage, pricing or reimbursement from third-party payors; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure to timely establish or leverage third-party partnerships or collaborations to commercialize Daré's product candidates, if approved; failure or delay in starting, conducting and completing clinical trials of a product candidate; Daré's ability to design and conduct 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 dependence on third parties to conduct clinical trials and manufacture clinical trial material, and if any of its product candidates are approved, to manufacture commercial product; Daré's ability to raise additional capital when and as needed to advance its product candidates, execute its business strategy and continue as a going concern; the effects of the COVID-19 pandemic on Daré's operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on Daré's ability to timely enroll, conduct and report results of its clinical trials and on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré; the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; the risk that developments by competitors make Daré's product candidates less competitive or obsolete; failure of Daré's product candidates, if approved, to gain market acceptance or obtain adequate coverage from third-party payers; 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; 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; 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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