Daré Bioscience's Sildenafil Cream Data in Postmenopausal Women Published in Menopause - The Journal of The Menopause Society

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Daré's proprietary formulation of topical sildenafil cream, 3.6% was well tolerated across all evaluated doses in the clinical study, with minimal systemic exposure

Company continues activities necessary to advance its Sildenafil Cream toward the FDA's 505(b)(2) regulatory pathway while in parallel launching DARE to PLAY™ Sildenafil Cream, the 503B compounded version of its proprietary sildenafil cream formulation***

DARE to PLAY Sildenafil Cream prescription dispensing and initial product revenue expected to commence in Q3 2026

SAN DIEGO, Aug. 26, 2026 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions, today announced the publication of results from a clinical study of its proprietary formulation of topical sildenafil cream, 3.6% (Sildenafil Cream) in *Menopause* - The Journal of The Menopause Society. Access the article here.

The peer-reviewed article, titled, "*A phase 1, open-label, within-participant dose-escalation study to evaluate the safety and pharmacokinetics of topical sildenafil cream in healthy postmenopausal women*," reports findings from the clinical study evaluating the systemic and local genital safety and pharmacokinetics of its proprietary Sildenafil Cream in healthy postmenopausal women.

"Women are speaking more openly about the sexual health changes they experience during perimenopause and after menopause, and they are increasingly seeking solutions that address more than vaginal dryness or discomfort," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience. "Low genital arousal and diminished sensation can meaningfully affect a woman's sexual health, relationships and overall quality of life, yet there remains no FDA-approved pharmacological treatment specifically for female sexual arousal disorder. These published results reinforce the potential of DARE to PLAY Sildenafil Cream, designed specifically around female anatomy and the physiology of female sexual arousal."

"Our strategy is designed to provide women with access to the compounded version of our proprietary sildenafil cream formulation now, DARE to PLAY Sildenafil Cream, while we continue activities necessary to seek FDA approval of our proprietary Sildenafil Cream in the future via the 505(b)(2) regulatory pathway," Ms. Johnson continued. "We believe an FDA-approved product could strengthen our competitive position to create a more durable and valuable commercial franchise."

The Phase 1 open-label, within-participant dose-escalation study enrolled 21 healthy postmenopausal women with a mean age of 57. Participants received a single dose of placebo cream followed by escalating doses of Sildenafil Cream containing 50 mg, 100 mg and 200 mg of sildenafil citrate, with a 14- to 16-day washout period between doses. Nineteen participants completed all four treatment periods.

Key findings included:

- All evaluated doses of Daré's proprietary Sildenafil Cream were well tolerated.
  - All treatment-emergent adverse events were mild, and there were no serious adverse events.
  - No cardiac treatment-emergent adverse events or episodes of symptomatic orthostatic hypotension were observed.
- At the 100 mg dose, which was the dose subsequently evaluated in Daré Bioscience's Phase 2b RESPOND study (ClinicalTrials.gov ID NCT04948151), the maximum plasma concentration of sildenafil was approximately 3,810 pg/mL, which is approximately two orders of magnitude lower than the concentration reported in men following a single 100 mg oral dose (450,000 pg/mL) in a separate clinical study, based on published data.
- The findings support localized delivery as an approach that may target the genital tissues involved in the female arousal response while limiting systemic exposure.

"Women frequently raise concerns about diminished arousal and sensation during and after the menopause transition, yet we have few clinically evaluated options to offer," said Dr. Sheryl Kingsberg, Division Chief of Behavioral Medicine, Department of OBGYN, University Hospitals Cleveland Medical Center, Ohio, and Past President of The Menopause Society and the International Society for the Study of Women's Sexual Health. "These results show that Daré's proprietary Sildenafil Cream was

well tolerated in postmenopausal women with minimal systemic exposure, reinforcing its potential as a localized administration designed specifically to address the genital physiological aspects of female sexual arousal. For our patients, this represents meaningful progress toward addressing a common and often overlooked area of women's health."

While existing products may help address vaginal dryness or discomfort, there are no FDA-approved products to directly increase genital blood flow in women. When blood flow to genital tissue is reduced, it can make arousal more difficult and decrease natural lubrication and sensation.

The Menopause Society is a leading nonprofit organization dedicated to empowering healthcare professionals and providing tools, resources and education to improve the health of women during the menopause transition and beyond. Its official peer-reviewed journal, *Menopause* - The Journal of The Menopause Society, is a respected scientific publication featuring original research, applied basic science and clinical guidelines focused on menopause and midlife women's health. Publication in the journal provides an opportunity to bring greater visibility to an area of women's health that remains significantly underserved despite increasing awareness and demand for effective solutions. Daré Bioscience is pleased to have its research featured in *Menopause* and to contribute to the growing body of scientific evidence supporting advances in women's health and improved care for women throughout the menopause transition and beyond.

ABOUT DARÉ BIOSCIENCE, INC.

Daré Bioscience (NASDAQ: DARE) is a purpose-driven health biotech company solely focused on closing the gap in women's health between promising science and real-world solutions. Every innovation Daré Bioscience advances is based in advanced science and backed by rigorous, peer-reviewed research. From contraception to menopause, sexual health to fertility, vaginal health to infectious disease, Daré Bioscience is working to close critical gaps in care using science that serves her needs. For decades, women have been told to "wait it out" or "live with it," while innovations that could improve their quality of life languish in the regulatory or funding pipeline. With growing awareness around menopause, sexual health, and vaginal health, the conversation is shifting. However, access to proven solutions is lagging. Daré Bioscience is working to change that. Learn more at darebioscience.com.

FORWARD-LOOKING STATEMENTS

Daré Bioscience 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," "prepare," "progress," "seek," "should," "would," "build" 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 Bioscience's plans and timing for prescription dispensing of and product revenue from DARE to PLAY Sildenafil Cream and continued development of and the regulatory approval pathway for Sildenafil Cream; the significance of data from Phase 1 and Phase 2 clinical studies of Sildenafil Cream; Sildenafil Cream's potential therapeutic benefits and safety profile, including in postmenopausal women; the market opportunity for Daré Bioscience's products and ability to gain market acceptance; and the potential impact of the products that Daré Bioscience brings to market for women and the company;

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Daré Bioscience'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, risks and uncertainties related to: Daré Bioscience's ability to raise additional capital when and as needed to execute its business strategy and continue as a going concern; potential suspension and delisting of Daré Bioscience's common stock from the Nasdaq Capital Market; Daré Bioscience's dependence on grants and other financial awards from governmental entities and a private foundation; Daré Bioscience's reliance on Section 503B-registered outsourcing facilities and other third parties to bring DARE to PLAY Sildenafil Cream and other solutions to market as compounded drugs or as consumer health products and facilitate access to such products and the risk that those third parties do not perform as expected; difficulties in establishing and sustaining relationships with third-party collaborators; the risk that the U.S. Food and Drug Administration (FDA) could stop permitting Section 503B-registered outsourcing facilities to compound the drug substances in the proprietary formulations Daré Bioscience intends to bring or brings to market or changes the conditions under which those drug substances may be used in compounding or the compounded products may be distributed; the ability of outsourcing facilities for Daré Bioscience's compounded products to maintain their registration with the FDA under Section 503B; the timing of establishing, and ability to maintain, state-required licensure or registration to enable fulfillment of prescriptions for DARE to PLAY Sildenafil Cream and other solutions brought to market via the Section 503B pathway; Daré Bioscience's inexperience, as a company, in and limited infrastructure for commercializing products; the degree of market demand and acceptance for the products Daré Bioscience brings to market; competitive product launches; greater than expected costs to bring compounded drug products to market and marketing costs; shifts in consumer spending or behavior; Daré Bioscience's reliance on third parties to manufacture and conduct clinical trials and preclinical studies of its product candidates and commercialize XACIATO™ (clindamycin phosphate) vaginal gel 2% and future FDA-approved products, if any; the risk that the FDA's 505(b)(2) pathway for drug product approval in the U.S. is not available for a product candidate as Daré Bioscience anticipates; Daré Bioscience's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product candidate and the inherent uncertainty of outcomes of clinical trials; Daré Bioscience'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; decisions not to

make clinical study design modifications recommended by the FDA; Daré Bioscience's dependence on third parties to conduct clinical trials and manufacture and supply clinical trial material and commercial product; the risks 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 and that interim data or results from a particular clinical study do not necessarily predict the final results for that study; the risk that the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré Bioscience's interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that even if a pivotal clinical study achieves its primary efficacy endpoint, the FDA may determine the data package is not sufficient to support a favorable benefit-risk determination in a future marketing application; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré Bioscience anticipates, or that the duration of a study or number of study subjects must be significantly greater than anticipated; the loss of, or inability to attract, key personnel; product pricing and coverage and reimbursement from third-party payors; Daré Bioscience's ability to retain its licensed rights to develop and commercialize a product or product candidate; Daré Bioscience'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 Bioscience's ability to adequately protect or enforce its, or its licensor's, intellectual property rights; disputes or other developments concerning Daré Bioscience's intellectual property rights; the lack of patent protection for the active ingredients in certain of Daré Bioscience'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 Bioscience's products or product candidates or the business activities of Daré Bioscience, its commercial collaborators or other third parties on which Daré Bioscience relies; changes in healthcare, pharmaceutical, consumer protection or privacy laws and regulatory policies; increased scrutiny from regulators; global trends toward health care cost containment; the effects of macroeconomic conditions, geopolitical events, and major changes and disruptions in U.S. government policies and operations on Daré Bioscience's ability to raise additional capital or on Daré Bioscience's operations, financial results and condition, and ability to achieve current plans and objectives; and cybersecurity incidents or similar events that compromise Daré Bioscience's technology systems and/or significantly disrupt Daré Bioscience's business or those of third parties on which it relies.

Daré Bioscience'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 Bioscience's risks and uncertainties, you are encouraged to review its documents filed with the U.S. Securities and Exchange Commission (SEC), including Daré Bioscience'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 Bioscience 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.

*The term FDA 505(b)(2) regulatory pathway refers to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), which enables an applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of the applicant's new drug application (NDA), providing an alternate path to FDA approval for new or improved formulations or new uses of previously approved drugs.

**The term DARE to PLAY describes a 503B compounded drug product. Compounded drug products are not approved by the FDA. The FDA does not evaluate compounded drug products for safety, effectiveness, or quality. References to Section 503B, 503B, 503B compounding, 503B compounded product, and similar terms refer to Section 503B of the FDCA and the production and supply of compounded drugs by Section 503B-registered outsourcing facilities without patient-specific prescriptions in accordance with Section 503B. Section 503B-registered outsourcing facilities are subject to FDA inspection and required to compound drug products under current Good Manufacturing Practice (cGMP) regulations to ensure quality, strength and consistency.

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