Daré Bioscience Announces Peer-Reviewed Publication of Phase 1 Sildenafil Cream Study in Men Demonstrating Substantially Lower Systemic Exposure Versus Oral Sildenafil

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Published Phase 1 data in Sexual Medicine strengthen the scientific foundation for Daré Bioscience's proprietary topical Sildenafil Cream, 3.6%

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Publication expands peer-reviewed clinical evidence supporting Daré Bioscience's proprietary topical Sildenafil Cream formulation

SAN DIEGO, Sept. 14, 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 Phase 1 clinical study evaluating the safety and systemic pharmacokinetics of topical Sildenafil Cream, 3.6% in healthy adult men in *Sexual Medicine*, an official journal of the International Society for Sexual Medicine. The article, titled, "*An open-label, single-dose, randomized, parallel-group study of the safety and relative bioavailability of topical sildenafil cream vs oral sildenafil in healthy male adults*," discusses findings from the study evaluating a higher and lower dose of topical Sildenafil Cream applied to the penis with and without condom use compared with a 50 mg oral dose of sildenafil. Access the full publication here.

"We are a women's health company, and that remains at the center of everything we do. One of Daré Bioscience's core strengths is our ability to apply sophisticated formulation and drug-delivery science to well-understood active ingredients in ways designed to address important gaps in care," said Sabrina Martucci Johnson, President and Chief Executive Officer of Daré Bioscience. "These peer-reviewed results are exciting because they demonstrate the potential power of that approach. Topical dosing is targeted and has been shown to result in substantially lower systemic exposure than an oral dose of sildenafil. This study in men provided additional clinical insight into our proprietary topical Sildenafil Cream formulation and expanded the evidence supporting its differentiated delivery profile. We believe that knowledge ultimately strengthens the scientific foundation of our work in women's sexual health while also supporting the broader potential of Daré Bioscience's formulation."

The open-label, randomized study enrolled 62 healthy men who received a single dose of either 36 mg or 71 mg of sildenafil in topical cream, with or without condom use, or a 50 mg oral dose of sildenafil in tablet form. The study evaluated safety and systemic pharmacokinetics of sildenafil and its active metabolite, N-desmethyl sildenafil.

The study treatments were well tolerated, with all 14 treatment-emergent adverse events reported during the study characterized as mild. Seven of the 14 events occurred in five participants who received oral sildenafil. There were no serious adverse events, severe adverse events, deaths or discontinuations due to treatment-emergent adverse events.

Importantly, Daré Bioscience's proprietary topical Sildenafil Cream resulted in substantially lower systemic exposure to sildenafil compared with the oral sildenafil group. Mean maximum plasma concentrations for sildenafil following topical administration (all four Sildenafil Cream dosing groups) ranged from 969 to 1,274 pg/mL, compared with 238,000 pg/mL for the oral sildenafil group. Relative bioavailability of sildenafil following topical administration (all four Sildenafil Cream dosing groups) ranged from 2.55% to 3.20%, suggesting a much lower systemic exposure as compared with the oral sildenafil group.

At the 71 mg topical dose, mean maximum plasma concentration of sildenafil was approximately 187-fold lower than following the 50 mg oral dose, while systemic exposure measured by AUC_{last} and AUC_{inf} was approximately 33-fold and 34-fold lower, respectively. 71 mg sildenafil in 2 grams of cream was the dose tested in a subsequent Phase 2b study of Sildenafil Cream, 3.6% in premenopausal women for treatment of female sexual arousal disorder.

"These Phase 1 findings provide important clinical evidence regarding the potential safety and pharmacokinetic profile of topical Sildenafil Cream in men," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "The substantially lower systemic exposure observed with topical administration is consistent with the rationale for localized delivery of sildenafil and supports continued development of our investigational Sildenafil Cream, 3.6% as a potential differentiated approach for arousal concerns."

The study was designed as a safety and pharmacokinetic evaluation in healthy men without erectile dysfunction and therefore did

not assess efficacy or erectile response. The publication adds to the clinical evidence supporting continued development of Daré Bioscience's proprietary Sildenafil Cream, 3.6% formulation, which has been evaluated in women with female sexual arousal disorder.

While Daré Bioscience remains solely focused on advancing solutions for women's health, the Company believes that a broader body of clinical evidence around its proprietary formulations can provide valuable scientific insights that ultimately strengthen the foundation for its work in women's sexual health. The Phase 1 study in men provided additional clinical evidence characterizing the behavior of the proprietary Sildenafil Cream, 3.6% formulation and Daré Bioscience's localized drug-delivery approach using sildenafil, a well-characterized active pharmaceutical ingredient. Sildenafil Cream, 3.6% has been clinically evaluated in women with female sexual arousal disorder, the clinically analogous condition to erectile dysfunction in men.

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: the significance of data from the Phase 1 clinical study in men for Daré Bioscience's Sildenafil Cream, 3.6% program; the potential therapeutic benefits and safety profile of Sildenafil Cream, 3.6% in women and men; the market opportunity for Daré Bioscience's products; and the potential impact of the products that Daré Bioscience brings to market for women.

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 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 Federal Food, Drug, and Cosmetic Act (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.

**The term FDA 505(b)(2) regulatory pathway refers to Section 505(b)(2) of the 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.

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