



**DARÉ** BIOSCIENCE.

## **Daré Bioscience, Inc. Announces Global Licensing Rights to the Novel Antimicrobial Glycerol Monolaurate for Vaginal Health**

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**Glycerol monolaurate has the potential to deliver broad antimicrobial activity to treat a variety of bacterial, fungal, and viral vaginal infections**

SAN DIEGO, Aug. 24, 2022 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that it has entered into a license agreement with Hennepin Life Sciences LLC under which Daré acquired the exclusive global rights to develop and commercialize treatments delivering the novel antimicrobial glycerol monolaurate (GML) intravaginally for a variety of vaginal health conditions including bacterial, fungal, and viral infections.

GML is a naturally occurring fatty acid monoester that has shown broad antimicrobial activity, killing bacteria, fungi and viruses and importantly, represents a new class of antimicrobial agents. Additionally, due to its mechanism of action, GML has shown low potential for the development of antibiotic resistance. In vitro testing has shown GML to be effective at inhibiting growth of the major strains of *Candida* causing vulvovaginal candidiasis (VVC), as well as *Gardnerella vaginalis*, the primary bacteria associated with bacterial vaginosis. Furthermore, a randomized, double-blind pilot study investigating the effects of GML on vaginal microflora in colonized or infected women showed reductions in *Candida* and *Gardnerella vaginalis* while not altering the healthy *Lactococcus* bacterium or vaginal pH.<sup>1</sup>

"Vaginal health conditions, particularly infections such as bacterial vaginosis and VVC, which is second only to bacterial vaginosis as the reason women seek gynecological care<sup>2</sup>, remain prevalent and serious problems that can negatively impact a woman's quality of life and create economic burden for women, employers, and the broader healthcare system. Women impacted by these conditions may have multiple episodes in a year, and treatments for one condition may increase the likelihood of developing another condition<sup>2</sup>. We believe that an antimicrobial providing a broad spectrum of activity against bacteria and fungi, but with a low potential for developing resistance, represents a unique multi-target development candidate for our portfolio. GML could both delay recurrence following an effective primary treatment of an episode, as well as mitigate common side effects of the primary treatment," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "As a company, we are committed to addressing unmet needs in women's health, including enhancing treatment options for vaginal health conditions. Earlier this year, Organon, a global women's healthcare company, and Daré entered into a global license agreement to commercialize Daré's XACIATO™ (clindamycin phosphate) vaginal gel, 2% for the treatment of bacterial vaginosis in female patients 12 years of age and older.<sup>3</sup>

Under the agreement with Hennepin, Daré received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the licensed technology. Daré agreed to make potential future milestone payments through the term of the license based on clinical, regulatory, and commercial events, and to pay royalties based on commercial sales. Patents covering the licensed technology have been granted with terms through 2034 and additional patents pending would have terms through 2040.

1. Antimicrob Agents Chemother. 2010 Feb;54(2):597-601

2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3827160/>

3. Please click [here](#) for full prescribing Information.

### **About Hennepin Life Sciences**

Founded in 2009 from a technology transfer out of the University of Minnesota, Hennepin Life Sciences LLC is a private, development stage human health company that is uniquely focused on the development of patent-protected, novel, naturally derived anti-infective compounds for the prevention and treatment of a wide array of infections. Hennepin Life Sciences has created innovative nature-based therapies by applying molecular concepts of infection to clinical applications.

### **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, fertility, and vaginal and sexual health. 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. XACIATO is a clear, colorless, viscous gel, to be administered once intravaginally as a single dose. Daré's portfolio also 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. 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](http://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 the potential benefits of GML. 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: 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; 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 and supply clinical trial material and 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 loss of, or inability to attract, key personnel; the effects of the COVID-19 pandemic, macroeconomic conditions and geopolitical events 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 to fulfill their contractual obligations to Daré; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; failure to timely establish or maintain third-party partnerships or collaborations to develop and/or commercialize Daré's product and Daré's product candidates, if approved; 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, product candidates or business activities; 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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