Daré Bioscience, Inc. Announces Licensing and Global Rights to Novel Phase III Product Candidate for the Treatment of Bacterial Vaginosis

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Bacterial vaginosis affects nearly 20 million women in the U.S. every year

SAN DIEGO, Dec. 06, 2018 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in clinical-stage women's health innovation, today announced that it has entered into definitive agreements with Hammock Pharmaceuticals, Inc., TriLogic Pharma LLC and MilanaPharm LLC under which Daré acquired the global rights to MP-101 for the treatment of bacterial vaginosis (BV), as well as the rights to utilize the underlying proprietary hydrogel drug delivery technology for any vaginal or urological application in humans.

Bacterial vaginosis is a type of vaginal inflammation caused by the overgrowth of bacteria naturally found in the vagina, which upsets the natural balance and is characterized by vaginal discharge, vaginal odor, vaginal itching, and burning during urination.

The proprietary *in-situ* gel system, which consists of a combination of a tri block copolymer and a natural polysaccharide, is designed to take advantage of body temperature to undergo solution-to-gel transition, enabling transformation into a bioadhesive gel formulation featuring extended release of the incorporated drug following application at the site of action. In MP-101 this proprietary technology is formulated with clindamycin, an antibiotic used to treat certain bacterial infections including BV, and has been engineered to produce a dual release pattern after vaginal application, providing maximum duration of exposure to clindamycin at the site of infection. Daré expects to commence a Phase III clinical study of MP-101 in approximately 250 women in the second half of 2019, and if the study is successful, to be in a position to file a new drug application with the U. S. Food and Drug Administration (FDA) in 2020. Based on MilanaPharm's discussions with the FDA, Daré believes that one Phase III study with sufficient power and size may be sufficient for marketing approval in the U.S.

Current BV therapies typically have a success rate of less than 70%. In an investigator initiated pilot study treating 30 women, MP-101 demonstrated an 88% cure rate with just one administration.

"We believe this Phase III program will allow us to move into a leadership position in an area of great concern for both women and healthcare providers," said Sabrina Martucci Johnson, President and CEO of Daré. "Studies suggest that nearly 20 million women in the U.S. experience BV and many suffer from episodes of recurrence. Current standard of care is oral antibiotics taken either once or over the course of several days, which can have systemic side effects, or antibiotics delivered vaginally in creams or gels, typically over the course of several days . If a cure rate consistent with the pilot study is demonstrated in the Phase III program, MP-101 has the potential to provide a significant improvement in efficacy over currently marketed BV therapies and enhanced convenience for women."

"Hammock is excited to announce our partnership with Daré Bioscience. The transaction allows Hammock to focus on our OTC products and to potentially recognize value from MP-101 and the novel hydrogel technology. We look forward to working with the Daré and MilanaPharm teams on the transition and the lead product candidate and possibly other product candidates incorporating the hydrogel technology," said William R. Maichle, CEO of Hammock Pharmaceuticals.

Under the agreements with Hammock and TriLogic/MilanaPharm, Daré received an exclusive, worldwide, royalty-bearing license to research, develop and commercialize the technology, paid one-time upfront fees of $275,000 and will pay one-time deferred fees of $450,000 within one year. In addition, Daré agreed to make potential future milestone payments through the term of the license based on clinical, regulatory, commercial launch and sales events, and to pay royalties based on commercial sales. Patents covering the licensed technology have been granted with terms through 2028 and additional patents pending would have terms through 2035.

Destum Partners advised Hammock Pharmaceuticals on the transaction.

About Hammock Pharmaceuticals

Hammock Pharmaceuticals is an international branded, specialty pharmaceutical and consumer health company focused on the commercialization of differentiated brands and high value generic products.

About MilanaPharm

MilanaPharm is a specialty pharmaceutical company built upon a proprietary drug delivery platform for numerous active compounds. MP-101 is part of the company's hydrogel platform which is designed to deliver drugs that remain in place over periods ranging from several hours to several days, depending on the desired delivery profile, in order to achieve an effective treatment outcome.

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's reproductive and sexual health. The company's mission is to identify, develop and bring to market a portfolio of novel, differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes two potential first-in-class candidates in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive vaginal ring, and Sildenafil Cream, 3.6%, a potential treatment for female sexual arousal disorder utilizing the same active ingredient as Viagra®. To learn more about Daré's full portfolio of women's health products, and mission to deliver novel therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using its investor relations website (http://ir.darebioscience.com), SEC filings, press releases, public conference calls and webcasts. Daré uses these channels to communicate with its investors and the public about the company and other company-related matters. The information Daré posts on its investor relations website may be deemed to be material information. Daré encourages investors, the media, and others interested in the company to review the information Daré posts on its investor relations 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," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the potential of MP-101 to significantly improve treatment outcomes in BV compared to currently marketed products, the potential for MP-101 to receive marketing approval for the treatment of BV following a single Phase III clinical study in approximately 250 subjects, the potential application of the licensed drug delivery platform for indications other than BV, Daré's ability to advance MP-101 into Phase III development, to successfully conduct the planned Phase III clinical study, and to achieve FDA acceptance of a new drug application for MP-101 in BV on its anticipated timelines or at all, and the potential for marketing exclusivity in BV and other indications based on issued patents and pending patent applications. 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 raise additional capital when and as needed, to advance its product candidates; Daré's ability to develop and commercialize product candidates, including MP-101; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré's product candidates in a timely manner; Daré's ability to conduct and design 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 efficacy of its product candidates; Daré's ability to retain our 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; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials; 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; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; 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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