Daré Bioscience Provides Update for Investors on Development Programs and Anticipated 2019 Milestones

January 2, 2019

Key anticipated 2019 clinical milestones:

- *Topline results of Ovaprene® PCT clinical trial*
- *Initiation of at-home portion of Sildenafil Cream, 3.6% Phase 2b*
- *Initiation of pivotal Phase 3 study of DARE-BV1*

SAN DIEGO, Jan. 02, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in clinical-stage women's health innovation, today provided an update on its product portfolio for investors that includes anticipated 2019 clinical milestones.

"2018 was a year of substantial execution as we assembled a broad and differentiated pipeline of product candidates across women's health," stated Sabrina Martucci Johnson, President and Chief Executive Officer of Daré. "In 2019, our goal is to continue delivering on meaningful milestones, including: the conclusion and read-out of our pre-pivotal enabling clinical study of our non-hormonal contraceptive Ovaprene; the initiation of a pivotal Phase 3 study for DARE-BV1 for bacterial vaginosis; the initiation of the at-home portion of our Sildenafil Cream, 3.6%, Phase 2b program for female sexual arousal disorder; and the acceleration of our intravaginal ring platform."

Added Martucci Johnson, "We believe that Daré has one of the most robust and differentiated pipelines in women's health, positioning us well for strategic partnerships, and we expect 2019 to be a critical year for our company as we seek to move multiple programs into late stages of clinical development and drive value."

Daré is committed to developing disruptive product candidates for women in the areas of sexual health, vaginal health, fertility, and contraception. The Company currently has three product candidates – including two potential first-in-class therapies – in late-stage development, with several others in earlier stages of development.

Late-stage clinical programs

Ovaprene® for non-hormonal contraception

- Ovaprene is a novel vaginal ring that has the potential to become the first hormone-free monthly contraceptive approved by the U.S. Food and Drug Administration (FDA).
- Ovaprene's once-a-month format is designed to provide multiple weeks of contraceptive protection for the growing number of women seeking convenient, non-hormonal methods.
- May 2018: A post-coital test (PCT) clinical trial was initiated to assess the safety and activity of Ovaprene in women.
- **2H 2019:** Daré anticipates reporting topline data results from the PCT clinical trial.
- If effectiveness is demonstrated, Daré intends to prepare and file an Investigational Device Exemption (IDE) with the FDA to commence a single pivotal clinical trial. This pivotal trial would be expected to support marketing approvals of Ovaprene in the U.S., the EU, and other regions worldwide.

Sildenafil Cream, 3.6% for female sexual arousal disorder

- Sildenafil Cream, 3.6%, referred to as "topical sildenafil," is a proprietary, topical formulation of sildenafil, the active ingredient in Viagra®, and has the potential to become the first FDA-approved product for female sexual arousal disorder (FSAD). Based on market research, an estimated 10 million women in the U.S. are actively seeking treatment for problems with sexual arousal.
- Topical sildenafil is designed to increase blood flow to the vulvar-vaginal tissue in women, leading to potential improvement in their genital arousal response and overall sexual experience.
- Q4 2018: A Phase 2b program was initiated with the commencement of a content validity study.

- **2019:** Daré expects to complete the content validity study in the first half of 2019. Following completion of this study and discussions with the FDA regarding trial design, Daré expects to commence the at-home portion of the Phase 2b study in the second half of 2019.

DARE-BV1 for bacterial vaginosis

- DARE-BV1 (formerly MP-101) is a proprietary solution-to-gel formulation containing clindamycin, an antibiotic used to treat certain bacterial infections, including bacterial vaginosis (BV). Current FDA-approved therapies for BV have a clinical cure rate of less than 70 percent, despite BV being the most common cause of vaginal infections for women ages 15-44.

- DARE-BV1 is engineered to be administered in a single vaginal dose with a dual release pattern to prolong the duration of exposure to clindamycin at the site of infection and to potentially improve the rate of effectiveness. In a pilot study, DARE-BV1 demonstrated an 88 percent clinical cure rate after one administration.

- **2H 2019:** Daré expects to commence a Phase 3 clinical study of DARE-BV1 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 FDA in 2020.

Portfolio programs

Novel intravaginal ring technology for multiple uses

- Daré's intravaginal ring (IVR) technology is designed to allow for sustained drug delivery over time periods ranging from weeks to months. The novel technology was developed by Dr. Robert Langer from the Massachusetts Institute of Technology and Dr. William Crowley from Massachusetts General Hospital and Harvard Medical School.

- Daré's lead IVR candidate, DARE-HRT1, is a combination natural estradiol and natural progesterone ring to treat vasomotor symptoms (VMS) associated with menopause as part of a hormone replacement therapy regimen. There are currently no FDA-approved IVRs that deliver natural progesterone in combination with natural estradiol.

- **2019:** Daré intends to initiate and report topline results of a Phase 1/2a clinical study for DARE-HRT1, which has the potential to be a first-in-class product. Daré can leverage its wholly-owned Australian subsidiary by conducting the Phase 1/2a study in Australia, which is expected to result in a cash rebate of approximately 40% of the research expenses incurred in Australia, thus lowering the effective cost of the Phase 1/2a program.

DARE-VVA1 for vulvar and vaginal atrophy

- DARE-VVA1 is a vaginally-delivered formulation of tamoxifen for the treatment of vulvar and vaginal atrophy (VVA) in women diagnosed with or being treated for hormone receptor positive breast cancer. Currently, there are no FDA-approved products indicated for VVA treatment in this population.

- **2019:** Daré intends to pursue formulation activities for DARE-VVA1.

Contraception innovation

- Injectable hormonal contraceptives are designed to provide discreet, non-invasive protection over several months. ORB-204 and ORB-214 are injectable etonogestrel contraceptive candidates with 6- and 12-month durations, respectively. There are currently no FDA-approved injectable contraceptives indicated to provide protection beyond three months. This program is Daré's first partnership to leverage funds and development work previously supported by investment from the non-profit development and donor community.

- CatSper is a well-studied target for contraception. The CatSper target provides the potential to develop the first non-hormonal contraceptive products that could be used by both men and women. Daré is seeking grant funding to support its DARE-RH1 program to fund the advancement of a pharmaceutical candidate to inhibit this target.

For more information on Daré's portfolio, including additional, early-stage candidates for contraception, please visit: https://www.darebioscience.com/pipeline.

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's sexual health, vaginal health, fertility, and contraception. 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 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 active ingredient in Viagra®, as well as a proprietary solution-to-gel formulation of clindamycin to treat bacterial vaginosis via a single application, DARE-BV1. To learn more about Daré's full portfolio of women's health product candidates, 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 for Ovaprene and DARE-BV1 to receive FDA and foreign regulatory approvals as a contraceptive device and a treatment for BV, respectively, following a single pivotal clinical trial, the potential for Daré's product candidates to become first-in-class and/or the first FDA-approved therapies for the patient populations for which they are being developed, Daré's ability to advance its product candidates into late-stage clinical development and conduct successful Phase 2b and Phase 3 clinical studies, Daré's anticipated timelines for clinical development and regulatory review and approval of its product candidates, the attractiveness of Daré and/or its product candidates to potential strategic partners and the potential for a significant cash rebate to Daré of expenses relating to its planned Phase 1/2a clinical study of DARE-HRT1. 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, obtain regulatory approval for, and commercialize its product candidates; 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 safety and efficacy of its product candidates; 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; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; 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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