Daré Bioscience Announces FDA Clearance of IND Application for DARE-BV1 for Bacterial Vaginosis to Commence Pivotal Phase 3 Clinical Study

December 18, 2019

DARE-BV1 demonstrated an 86% clinical cure rate in evaluable subjects at the test-of-cure visit (Day 7-14) after a single administration in an investigator-initiated proof of concept study

SAN DIEGO, Dec. 18, 2019 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ:DARE), a leader in women's health innovation, today announced that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for DARE-BV1, its novel thermosetting bioadhesive hydrogel containing 2% clindamycin phosphate being developed for one-time vaginal administration for the treatment of bacterial vaginosis (BV), a common but difficult to treat vaginal infection estimated to affect more than 20 million women in the United States.[1]

With the IND clearance from the FDA, Daré can commence the planned Phase 3 clinical study of DARE-BV1 in approximately 220 women in 2020 to support the New Drug Application (NDA) submission. Based on discussions with the FDA, the Phase 3 study will include a placebo control and assess the primary endpoint of clinical cure of BV (defined as resolution of specified clinical signs and symptoms from baseline visit) at the test-of-cure visit to occur 21 to 30 days after enrollment in the study, or the Day 21-30 visit. If this single Phase 3 study and the nonclinical studies that Daré plans to conduct in parallel with the Phase 3 study are successful, Daré intends to file the NDA following the completion of this Phase 3 study.

"With the potential to demonstrate a higher clinical cure rate than the current FDA-approved vaginally-administered treatments and its single application one-and-done dosing regimen, DARE-BV1 could disrupt the bacterial vaginosis market. This announcement marks another important milestone for Daré, becoming the third program in our portfolio where we have achieved a meaningful clinical or regulatory objective this quarter," said Sabrina Martucci Johnson, President & CEO of Daré Bioscience. "Earlier in the quarter, we announced the successful completion of a clinical study of Ovaprene, supporting its potential to be the first hormone-free, monthly contraceptive option for women and continued development toward premarket approval pending the successful commencement and completion of a pivotal contraceptive effectiveness and safety trial. More recently, we announced the conclusion of a Type C meeting with the FDA and alignment with the agency on the study design, including the primary endpoints and the patient reported outcome instruments, for our Phase 2b study of Sildenafil Cream, 3.6% for the treatment of female sexual arousal disorder, a condition for which there are currently no FDA-approved products."

Bacterial vaginosis (BV) is the most common cause of vaginitis worldwide.[2] While there are a number of treatment options for women diagnosed with BV, most options have relatively low clinical cure rates (37-68%), which may be one of the key drivers of recurrence rates. It is estimated that as many as 50% of women treated for BV will experience a recurrence within twelve months of their treatment.[3]

Earlier this year, Daré announced that DARE-BV1 had been granted Qualified Infectious Disease Product (QIDP) designation by the FDA for the treatment of BV in women. QIDP designation creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The primary incentive is a five-year exclusivity extension added to any exclusivity for which a QIDP qualifies upon FDA approval and makes the product candidate eligible for Fast Track designation and Priority Review.

BV has been associated with serious health issues, including preterm births, pelvic inflammatory disease, increased susceptibility to sexual transmitted infections (including HIV infection) and other chronic health problems.[4] It is estimated that BV is present in at least 15% of the sexually active population making it more common than urinary tract infections and many times more common than the *Trichomonas vaginalis* infection and vulvovaginal candidiasis.[5]

1. Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC); https://www.cdc.gov/std/bv/stats.htm
2. *Clinical Infectious Diseases* 2007; 44:213–9; https://doi.org/10.1086/509577
3. *The Journal of Infectious Diseases* 2006; 193:1478–86; https://www.ncbi.nlm.nih.gov/pubmed/16652274
4. CDC www.cdc.gov/std/bv/stats.htm; Onderdonk, A. et al. "The Human Microbiome during Bacterial Vaginosis," Clinical Microbiology Reviews, April 2016 Volume 29 Number 2
5. *Clinical Infectious Diseases* 2007; 44:220–1; https://doi.org/10.1086/509584

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of 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 expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a hormone-free, monthly vaginal contraceptive; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré's full portfolio of women's health product candidates, and mission to deliver differentiated 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 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 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 on its investor relations website (https://darebioscience.gcs-web.com/) 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 on the investor relations page of Daré's website mentioned above.

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 a single application of DARE-BV1 to safely and effectively treat BV, the potential for DARE-BV1 to demonstrate a higher clinical cure rate than current FDA-approved vaginally-administered treatments, the potential for regulatory approval of DARE-BV1 based on a single, successful Phase 3 clinical study, the timing of the Phase 3 clinical study of DARE-BV1, the potential for regulatory approval of Ovaprene based on a single, successful contraceptive effectiveness and safety clinical study, and Ovaprene's potential to be the first FDA-approved hormone-free, monthly contraceptive option for women. 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 and continue as a going concern; 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; the risk that a product candidate may fail to demonstrate equivalent or superior efficacy and/or safety in a pivotal clinical study compared to results from a pre-pivotal study or studies; 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.

Contacts:

Investors on behalf of Daré Bioscience, Inc.:
Lee Roth
Burns McClellan
lroth@burnsmc.com
212.213.0006

OR

Media on behalf of Daré Bioscience, Inc.:
Jake Robison
Canale Communications
jake@canalecomm.com
619.849.5383

Source: Daré Bioscience

Source: Dare Bioscience, Inc.