

Daré Bioscience, Inc. Announces Trial Initiation for Ovaprene® Non-Hormonal Monthly Contraceptive Candidate

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SAN DIEGO, May 15, 2018 (GLOBE NEWSWIRE) -- <u>Daré Bioscience. Inc.</u> (NASDAQ:DARE), a clinical-stage, women's biopharmaceutical company focused on women's sexual and reproductive health, announced today the initiation of its post-coital test (PCT) clinical trial for its lead product candidate Ovaprene®, a monthly non-hormonal contraceptive vaginal ring.

"The initiation of this clinical trial is an important milestone for our company," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience, Inc. "We continue to leverage our strong position in women's sexual and reproductive health to identify and advance true innovation capable of addressing unmet needs. We believe Ovaprene has the potential to offer women a viable, hormone-free birth control option that provides protection over several weeks and is as an alternative to hormone-based contraceptive products. We are excited to advance Ovaprene into the next stage of its development pathway."

This clinical trial is designed to assess general safety, acceptability, and effectiveness in preventing progressively motile sperm from reaching the cervical canal following intercourse. The study is enrolling 50 couples, with the woman to be evaluated over the course of five menstrual cycles, with a target of having at least 25 women complete a total of 21 visits. Each woman's cervical mucus will be measured at several points during the study, including a baseline measurement at menstrual cycle 1 that excludes the use of any product. Subsequent cycles and visits will include the use of a diaphragm (menstrual cycle 2) and the Ovaprene non-hormonal vaginal ring (menstrual cycles 3, 4 and 5).

"We are honored to collaborate with distinguished scientists and investigators from some of the most prestigious research centers in the country," said Mark Walters, Vice President of Operations at Daré Bioscience. "The investigators from CONRAD/Eastern Virginia Medical School, Oregon Health & Science University, the University of California, Davis, and the University of Pennsylvania, are renowned for their work in the field of contraception, having conducted research on some of the meaningful innovations in women's reproductive health."

Data from the study is expected to be available in the second half of 2019. If there is demonstration of feasibility in the PCT clinical trial, the Company intends to prepare and file an Investigational Device Exemption (IDE) with the FDA to commence a pivotal clinical trial to support marketing approvals of Ovaprene in the United States, Europe and other countries worldwide.

"Many women are seeking alternatives to traditional hormone-based options," commented Andrea Thurman, MD, Professor of Obstetrics-Gynecology at CONRAD/Eastern Virginia Medical School. "While we have an effective long-acting implanted non-hormonal contraceptive, 50% of contraceptive users prefer a short-acting method. We don't have an effective short-acting non-hormonal method that does not require intervention at the time of intercourse to offer these women. The opportunity to address this unmet need is compelling."

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 diverse 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 currently in clinical development: Ovaprene®, a non-hormonal, monthly contraceptive vaginal ring and Topical Sildenafil (SST-6007), 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.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995 regarding matters that are not historical facts, including statements relating to Daré's ability to file an IDE and develop Ovaprene in accordance with the clinical trial development plan set forth herein, expectations regarding the anticipated market demands for its products, the safety and effectiveness of its products and market acceptance of Daré's products. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various important factors, including the uncertainties inherent in the initiation and completion of clinical trials; availability and timing of data from ongoing and future clinical trials and the results of such trials; whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals, and other factors discussed in the "Risk Factors" section of Daré's Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2018. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Daré's reports to the Securities and Exchange Commission, including Daré's reports on Forms 10-Q, 8-K and 10-K. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. Daré specifically disclaims any obligation to update any forward-looking statements included in this press release.

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