Daré Bioscience and Premier Research Extend Strategic Partnership to Accelerate the Clinical Development of Daré's Novel Women's Health Programs

11-20-2023 at 8:00 AM EST

Partnership Aims to Advance Daré's Reproductive Health Portfolio in a Timely and Capital Efficient Manner

SAN DIEGO and MORRISVILLE, N.C., Nov. 20, 2023 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, and Premier Research International, LLC, a global clinical research, product development, and consulting company, today announced that the companies extended their partnership agreement under which Premier Research will continue to provide on an exclusive basis contract research organization (CRO) services within the United States to support the clinical development of Daré's reproductive health portfolio. The agreement was originally established with Health Decisions, Inc., which was acquired by Premier Research in 2021.

"In 2020, Daré and Premier Research conducted a successful Phase 3 clinical study of XACIATO™ (clindamycin phosphate) vaginal gel 2% despite the challenges posed by a global pandemic. As we approach the start of the pivotal clinical study of Ovaprene®, we are excited to reaffirm our strategic partnership with Premier Research and leverage its deep expertise in the clinical development of women's health products, including contraception," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "Daré is committed to advancing a portfolio of differentiated product candidates that address meaningful unmet needs in women's health in a timely and cost-efficient manner. This extended partnership has the potential to benefit multiple Daré programs, including those outside of reproductive health, such as the planned Phase 3 study of Sildenafil Cream, 3.6%, through the combination of commitment, clinical development expertise and cost savings."

Premier Research's women's health expertise includes more than 100 clinical trials over the past five years, a network of thousands of women's health sites and a proven track record of working with multiple divisions of the U.S. Food and Drug Administration (FDA). In 2020, Daré and Premier Research collaborated successfully on the Phase 3 clinical study XACIATO™ (clindamycin phosphate) vaginal gel 2%, Daré's first FDA-approved product. The upcoming pivotal Phase 3 study of Ovaprene®, an investigational hormone-free, monthly intravaginal contraceptive, will be conducted in collaboration with the *Eunice Kennedy Shriver National Institute of Child Health and Human Development* (NICHD) and supported by NICHD's Contraceptive Development Program, which oversees the Contraceptive Clinical Trial Network (CCTN). The pivotal Phase 3 study will be conducted within the CCTN with Premier Research serving as the NICHD's CRO partner.

Under the terms of the extended agreement, Premier Research will continue to be Daré's exclusive provider of CRO services within the United States for all of Daré's reproductive health product candidates for another three-year period, provided that Premier Research has the expertise, resources and availability to perform the clinical research services that Daré requires. In exchange for that CRO exclusivity, Premier Research will continue to provide attractive pricing structures, clinical expertise, an extensive site network, relationships with key opinion leaders and investigators, and a core team of personnel dedicated to supporting all of Daré's development programs covered by the agreement.

"Premier Research is thrilled to renew this partnership and continue our successful work with Daré," said Michael Arlotto, Ph.D., Chief Operating Officer of Premier Research. "This partnership underscores our joint commitment to advancing women's health by supporting efforts to include women in clinical research and bring novel products to market. We look forward to building on the achievements in our relationship to date and helping further accelerate Daré's unique pipeline to potentially impact the lives of women everywhere."

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, vaginal health, reproductive health, menopause, sexual health and fertility.

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. Daré's portfolio also includes potential first-in-category candidates in clinical development: Ovaprene®, a novel, hormone-free monthly intravaginal 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 (FSAD) and/or female sexual interest/arousal disorder (FSIAD) utilizing the active ingredient in Viagra®; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for menopausal hormone therapy. 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.

Daré Bioscience leadership has been named on the Medicine Maker's Power List and Endpoints News' Women in Biopharma 2022. In 2023, Daré's CEO was honored as one of Fierce Pharma's Most Influential People in Biopharma for Daré's contributions to innovation and advocacy in the women's health space. Daré Bioscience placed #1 in the Small Company category of the San Diego Business Journal's 2023 Best Places to Work Awards.

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 X (formerly 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.

About Premier Research

Premier Research, a global clinical research, product development, and consulting company, is dedicated to helping biotech, specialty pharma, and medtech innovators transform life-changing ideas and breakthrough science into new medical treatments.

Premier Research specializes in the use of innovative technologies for smart study design and trial management to deliver clean, conclusive data to sponsors.

Whether it's developing product lifecycle strategies, reducing clinical development cycle times, securing access to patients, navigating global regulations, maximizing the impact of limited rare disease data, or providing expertise in specific therapeutic areas, Premier Research is committed to helping its customers answer the unmet needs of patients across a broad range of medical conditions. Visit premier-research.com.

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 to Daré of its agreement with Premier Research, including acceleration of the clinical development of its product candidates and cost savings. 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, risks and uncertainties related to: 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; Daré's ability to develop, obtain FDA or foreign regulatory approval for, and commercialize its product candidates and to do so on communicated timelines; failure or delay in starting, conducting and completing clinical trials of a product 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; 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; the risk that the FDA, other regulatory authorities, members of the scientific or medical communities or investors may not accept or agree with Daré's interpretation of or conclusions regarding data from clinical studies of its product candidates; the risk that development of a product candidate requires more clinical or nonclinical studies than Daré anticipates; the loss of, or inability to attract, key personnel; the effects of macroeconomic conditions, geopolitical events, public health emergencies, and major disruptions in government operations on Daré's operations, financial results and condition, and ability to achieve current plans and objectives; the risk that developments by competitors make Daré's product or product candidates less competitive or obsolete; difficulties establishing and sustaining relationships with development and/or commercial collaborators; 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 or product candidates or the business activities of Daré, its commercial collaborators or other third parties on which Daré relies; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; cybersecurity incidents 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.

Contacts:

Media and Investors on behalf of Daré Bioscience, Inc:
Camilla White / Simona Kormanikova
Dentons Global Advisors
DareBioscience@dentonsglobaladvisors.com / 1.212.466.6450

Media on behalf of Premier Research:

Joe Lindroos
Vice President, Marketing
Joe.Lindroos@premier-research.com
+1 416 365 2917

Source: Daré Bioscience, Inc.

Source: Daré Bioscience, Inc.