Validcare Selected by Emerging Biotech, Coologics, to Lead Women's Health Study

Validcare's CRO approach provides Coologics unmatched confidence, visibility and control to complete its study on time, on budget, and with high data integrity.

CASTLE PINES, CO, UNITED STATES, January 5, 2024 /EINPresswire.com/ -- Coologics, Inc. has engaged Validcare to run its multi-center, prospective, interventional study of 160 women with Vulvovaginal Candidiasis (VVC) to determine the speed, efficacy and symptom resolution using its Vaginal Cooling Device (VCD) known as Vlisse™ vs. a control group using a CDC-approved therapy for treatment. The results of the study will be used to support Coologics' planned submission for market approval by the U.S. Food and Drug Administration (FDA).

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> *Dr. Kim Langdon, Coologics, Chief Medical Officer*

"With millions of women suffering from VVC each year, I am extremely confident as a physician that our groundbreaking Vlisse™ demonstrates a faster, more effective drug-free treatment of VVC that provides immediate relief of symptoms compared to traditional drug therapies. Women need a better solution because many of the drugs are slow to treat VVC and fail more often than we would like." Said Dr. Kim Langdon. "As an inventor and founder of a biotech company, I needed to find a CRO that understands and aligns with my clinical, financial and timeline goals. I trust Validcare's experience in women's health and their end-to-end approach to provide me and my investors great confidence in study planning and execution." Coologics' Chief Medical Officer, Dr. Keith Aqua, has performed over 300 clinical trials and will oversee the study sites. After Dr. Aqua's patients used Vlisse with 100% success, he said, "Kim, this will definitely change the standard of care."

Reduced Time from Database Lock to Analytics

Coologics has entrusted Validcare for end-to-end CRO services from protocol development, investigator selection, and patient recruitment through database lock. The study will employ a hybrid approach with data collected in office by investigators and remotely from participants in near real time.

“We are excited to work with Coologics, its principal investigators and study participants to collect the data needed for FDA submission.” said Robert Kaufmann MD, Medical Director at Validcare. “Through careful planning and optimization of electronic direct data capture, Validcare is poised to ensure that participation in this study and collection of data will be easy and meet regulatory standards, whether in office or at home.”

This study is planned to start enrollment in the first half of 2024 with database lock (i.e., last patient data submission) before the end of the year. Once completed, Validcare’s data management practices will accelerate the delivery of the final data set, analytics and write up vs. traditional CROs, so Coologics can optimize its timing for regulatory submission.

About Validcare

Validcare is a high-performance Contract Research Organization (CRO) uniquely skilled at de-risking the execution of clinical studies for pharma, biotech and medical device companies, spanning all therapeutic areas. Its revolutionary approaches give sponsors unmatched visibility and control to complete studies on time, on budget, and with high data integrity. Founded by experts with more than 30 years of executive-level industry experience, Validcare is a trusted advisor and strategic business counsel to its sponsor clients, helping to bring life-changing products to market.

For more information, visit validcare.com or call 844-825-4322.

About Coologics

Coologics is a biotech company set to revolutionize women’s health with a groundbreaking solution in an all-drug category which has not experienced innovation in decades. The company was founded in 2019 by Kim Langdon, MD, a board-certified OB/GYN. Dr. Langdon’s experience as a practicing OB/GYN, and seeing thousands of women afflicted by these infections, fueled her passion for this game-changing, drug-free solution. Coologics has partnered with Project MedTech, a Cleveland-based firm accelerating medical technology that will assist with the next milestones of clinical trial, FDA submission, and the commercialization process.

For more information, visit coologics.com.

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