Heranova™ Launches Early Access Program for HerResolve™, a Potential First FDA-Cleared, Non-Invasive Endometriosis Test

Peripheral Blood Test Simplifies Diagnosis for Disease Affecting One in 10 Women Worldwide

BOSTON, MA, UNITED STATES, August 8, 2024 /EINPresswire.com/ -- Heranova™ , a pioneering women's health company, today announced the launch of an early access program for HerResolve™, potentially the first FDA cleared, non-invasive endometriosis diagnostic test, designed to transform the diagnosis of endometriosis, a chronic and often debilitating disease affecting an estimated 200 million women worldwide.

> “All of my patients with undiagnosed pelvic pain or unexplained infertility could potentially benefit from this testing now.”
>
> *Ronald F. Feinberg MD, PhD*

Endometriosis is a painful condition characterized by the growth of uterine-like tissue outside the uterus, resulting in a constellation of debilitating symptoms including infertility, bleeding and moderate to severe pain. For most women, accurate diagnosis takes an average of 7-10 years from the onset of symptoms. This delay is largely due to the wide range of symptom presentation as well as the invasive nature of the most reliable diagnostic method currently available, exploratory laparoscopic surgery. Because of its non-invasive solution, HerResolve has the potential to shorten the diagnostic window from years to months, and improve outcomes for patients and the healthcare system.

The early access program is being supported by key institutions around the country and enables healthcare providers and patients to gain access to the HerResolve test prior to formal launch - planned to coincide with the American Society of Reproductive Medicine (ASRM) conference later this year. The program will provide real-world utilization data to inform and validate the clinical utility of the test and to further refine the workflow in preparation for commercialization. The program is a significant milestone for Heranova, demonstrating the company's commitment to addressing the unmet needs in women's health.

"All of my patients with undiagnosed pelvic pain or unexplained infertility could potentially benefit from this testing now," said Ronald F. Feinberg MD, PhD, Chief Medical Officer & Director of IVF Programs of RADfertility™, member of the CCRM ® Fertility Network, who also is a lead physician in the early access program. “HerResolve can positively impact fertility success and

improve quality of life by getting patients diagnosed sooner and treated more effectively."

Vicki Schnell, MD from Shady Grove Fertility echoed this sentiment, stating that, “This test will be of huge value to our multitude of centers across Texas and eventually the nation. It represents a significant advancement in how we approach endometriosis diagnosis and management."

"The overwhelming enthusiasm from our Principal Investigators underscores the unmet need HerResolve meets,” said Farideh Bischoff, Ph.D., Chief Medical Officer and Head of Heranova’s Diagnostics Division. “This is a testament to the critical unmet need our product is addressing and aligns perfectly with Heranova's mission to bring meaningful innovation to the field of women's health, starting with endometriosis."

HerResolve™ plans to file for FDA regulatory clearance later this year with the goal of being the first FDA cleared, noninvasive diagnostic test for endometriosis.

About Heranova Lifesciences™

Heranova Lifesciences™ is dedicated to developing integrated care solutions for Women's Health. The company secured $13.5 million in seed funding to address conditions including endometriosis and infertility. It offers internally developed and externally partnered diagnostics, drugs, and devices to address unmet needs in women's healthcare. Founded in March 2022 by serial entrepreneurs and seasoned executives with support from a world-class scientific advisory board, Heranova has an established global presence with its headquarters in Boston, Massachusetts.

About HerResolve™

HerResolve™ intends to be the first FDA cleared, non-invasive, peripheral blood test that diagnoses endometriosis in women experiencing symptoms such as pelvic pain, painful periods, infertility and dysmenorrhea. HerResolve will provide an accurate “detected/not detected” diagnosis of endometriosis, enabling physicians to diagnose earlier and begin personalized medical or surgical management.

For more information about Heranova Lifesciences™ and HerResolve™, please visit www.heranova.com.

Cory Dunn, MS, MEd
Heranova Lifesciences Holding Ltd.
+1 760-705-7464
email us here
Visit us on social media:
LinkedIn