

Aspira Women's Health Initiates Prospective Clinical Study for Benign Risk Monitoring and High Risk Early Ovarian Cancer Detection with Northwell Health®

Description

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Study Evaluates a 3rd Generation Multivariate Index Assay for serial monitoring women with a benign pelvic mass as well as the expansion of our development of our proteogenomic test for early-stage detection of ovarian cancer in high risk Ovarian Cancer patients.

AUSTIN, Texas; May 12, 2021 – Aspira Women's Health, Inc. (Nasdaq: AWH), a bioanalytical-based women's health company focused on gynecologic disease and The Feinstein Institutes for Medical Research, the science arm of Northwell Health, the largest private Healthcare Provider in New York State, today announced the start of a prospective Clinical Study for Ovarian Cancer Risk Detection. Northwell Health treats over 2 million patients annually and employs over 16,000 credentialed physicians.

The study will enroll over 600 prospective women with adnexal masses. The study will also enroll over 2000 women at high risk for Ovarian Cancer, either due to a personal or family history of cancer or are carriers of a germline variant associated with hereditary breast and ovarian cancer syndrome. Ovarian cancer risk will be assessed by both CA125 and Aspira's OVASight proprietary algorithm. The primary objective is to increase our total trial enrollment to validate the serial monitoring aspect of the OVASight algorithm in women who present with an adnexal mass. The secondary endpoint is to test additional genomic markers to develop a proteogenomic test for early-stage detection of ovarian cancer. This study will support and collect different biological targets and clinical data metrics to support our innovation pipeline for test development of early diagnosis of ovarian, and other gynecological cancers. "Having testing options for women with benign masses to monitor them over time, as well as having a solution for assessing risk in high-risk women will provide meaningful insights for providers treating these women," said Elena Ratner, MD, Gynecologic Oncologist and Global Chief Medical Advisor, Clinical and Translational Medicine

"Northwell Health is proud to work with Aspira on this important clinical study," stated the Principal Investigator of the trial, Dr. Gary L. Goldberg, Vice Chair for Research, Department of Obstetrics and Gynecology, at Northwell Health and researcher at the Feinstein Institutes. "As clinicians we need innovative and reliable testing options for women and our hope is this study will provide key insights for diagnosing and treating women who are high risk for developing ovarian cancer."

Aspira Women's Health has over 10 years of experience developing Ovarian Cancer Risk Assessment tests with its proprietary, FDA-Cleared OVA1® and OVERA® multivariate index assay's. Ovarian cancer accounts for more deaths than any other cancer of the female reproductive system and is the only gender-specific cancer with an over 50 percent mortality rate impacting women of all ages and ethnicities.

"This study is twofold, one is to vastly increase our enrollment to clinically validate the serial monitoring aspect OVASight test for all women who present with a mass and hereditary breast and ovarian cancer syndrome, and second, enrich our research and innovation pipeline," said Lesley Northrop, PhD, FACMG, Chief Scientific Officer, Aspira Women's Health. "I am incredibly excited to work with the Feinstein Institutes in enhancing our biobank of biological samples and clinical data metrics. This will allow us the ability to evaluate additional biomarkers including ctDNA, RNA and proteins to apply as a multi-modal approach in early diagnosis of ovarian cancer as a liquid-biopsy based test."

About the Feinstein Institutes

[The Feinstein Institutes for Medical Research](#) is the research arm of Northwell Health, the largest health care provider and private employer in New York State. Home to 50 research labs, 3,000 clinical research studies and 5,000 researchers and staff, the Feinstein Institutes raises the standard of medical innovation through its five institutes of behavioral science, bioelectronic medicine, cancer, health innovations and outcomes, and molecular medicine. We make breakthroughs in genetics, oncology, brain research, mental health, autoimmunity, and are the global scientific leader in bioelectronic medicine – a new field of science that has the potential to revolutionize medicine. For more information about how we produce knowledge to cure disease, visit <http://feinstein.northwell.edu> and follow us on [LinkedIn](#).