Aspira Women's Health Announces Publication of its Second-Generation MultiVariate Index Assay, OVERA®, in the Detection of Cancer in Filipino Women

Description

Data demonstrates the accuracy of Aspira's multivariate assessment test OVERA in a non-White population and concludes use of OVERA to be better than CA-125 in detecting early-stage cancer in women with a pelvic mass

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AUSTIN, Texas, Sept. 12, 2022 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira"), a bio-analytical based women's health company focused on gynecologic disease, today announced publication of a study on the use of its multivariate index assay, MIA2G (OVERA®), in the detection of ovarian cancer in Filipino women in the peer-reviewed International Journal of Environmental Research and Public Health.

The paper, entitled: "*Clinical Performance of a Multivariate Index Assay in Detecting Early-Stage Ovarian Cancer in Filipino Women*," highlights the first prospective study evaluating the clinical performance and overall utility of MIA2G (OVERA) ovarian cancer risk assessment in a non-White population. In the study, researchers prospectively compared various diagnostic methods, including ultrasound/IOTA (International Ovarian Tumor Analysis Rules), the biomarker CA-125, and OVERA, evaluating them for their ability to detect ovarian cancer. Results were correlated with surgical findings.

The data showed MIA2G (OVERA) to exhibit the best overall performance in detecting ovarian cancer with a sensitivity of 91.7%, regardless of menopausal status, compared to CA-125 with a sensitivity of 76.7%. Notably, MIA2G (OVERA) was shown to be more sensitive in detecting early-stage disease for this population. MIA2G (OVERA) demonstrated 92.4% early-stage sensitivity vs CA-125 at 74.3%. The study also showed that MIA2G (OVERA) had the best overall performance of all individual classifiers, including in some of the most difficult to detect cancers cohorts such as premenopausal women, and early-stage disease.

The study concluded that incorporating MIA2G (OVERA) rather than CA-125 into clinical assessment would increase the detection of early-stage ovarian cancers, regardless of menopausal status.

"The data were remarkable and adds to the growing body of evidence confirming the advantage of MIA2G (OVERA) versus CA-125 testing in the patient's initial clinical assessment to detect ovarian cancer at its earliest stages," said Dr. Charles Dunton, Chief Medical Officer of Aspira Women's Health. "Early detection of ovarian cancer is crucial for improving overall survival rates. Over 65% of ovarian cancers are detected at late stage, which has such a significant mortality rate. Clearly, we need to do better job of detecting ovarian cancer earlier in all women, and this study indicates that OVERA may substantially improve the effectiveness of clinical assessment in Filipino women with adnexal masses."

Nicole Sandford, President and Chief Executive Officer of Aspira added, "This large study is a first of its kind and is very exciting. It confirms our belief that OVERA in conjunction with clinical assessment performs very well in assessing early-stage ovarian cancer risk regardless of menopausal status and should become the standard of care for all women. We are firmly committed to health equity and will continue to be a driving force behind research like this milestone study."

About the OVASuite of Products (OVA1plus®, including OVA1® and OVERA®)
Ova1 is a blood test intended as an aid to further assess the likelihood of malignancy in women with an ovarian adnexal mass for which surgery is planned. OVERA is a second-generation biomarker panel intended to maintain OVA1's high sensitivity while improving specificity. OVA1plus is a reflex test performed for those OVA1 test results that are in the intermediate range.

About Aspira Women's Health Inc.
Aspira Women's Health Inc.SM is transforming women's health with the discovery, development, and commercialization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management, and improve gynecologic health outcomes for women. Aspira Women's Health is particularly focused on closing the ethnic disparity gap in ovarian cancer risk assessment and developing solutions for pelvic diseases such as pelvic mass risk assessment and endometriosis. OVA1plus® combines our FDA-cleared products, OVA1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses. Aspira GenetiX™ testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. With over 10 years of expertise in ovarian cancer risk assessment, Aspira Women's Health is working to deliver a portfolio of pelvic mass products over a patient's lifetime with our cutting-edge research. The next generation of products in development include OVAWatch™ and EndoCheck™. To improve patient accessibility, Aspira Women's Health has recently launched our Aspira Synergy℠ technology transfer platform to empower health systems, academics, regional labs, and physician group labs to conduct genetic and specialty tests in-house. Visit our website for more information at **www.aspirawh.com**.

Forward-Looking Statements
This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding, without limitation, the Company's plans, forecasts, projections, potential expansion and focus, current and future test offerings. These statements involve a number of risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and

similar expressions are intended to identify forward-looking statements. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties, and assumptions, including the risks and uncertainties described in the section entitled “Risk Factors” in Aspira Women’s Health’s Annual Report on Form 10Q, dated May 11, 2022. The events and circumstances reflected in Aspira Women’s Health’s forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Aspira Women’s Health expressly disclaims any obligation to update, amend or clarify any forward-looking statements to reflect events, new information or circumstances occurring after the date of this press release, except as required by law.

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