Aspira Women's Health Announces Publication of Data Demonstrating Performance of its In-Development Blood Test for the Assessment of Malignancy Risk in Patients with an Adnexal Mass

Description

The addition of miRNA and metadata to Aspira's existing protein assay shows promising improvements in both sensitivity and specificity for early-stage ovarian cancer in women with an adnexal mass

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AUSTIN, Texas, Sept. 10, 2024 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira") (Nasdaq: AWH), a bio-analytical based women's health company focused on the development of gynecologic disease diagnostic tools, today announced the publication of a paper in the journal Gynecologic Oncology highlighting data demonstrating that a multimodal assay combining miRNA with protein biomarkers, age, and menopausal status offered the most accurate classification of patients with an adnexal mass for the identification of early-stage ovarian cancer.

The study, entitled: "*Serum miRNA improves the accuracy of a multivariate index assay for triage of an adnexal mass*," analyzed serum samples from 468 training subjects (191 cancer cases and 277 benign adnexal mass controls or healthy controls) for seven protein biomarkers and 180 miRNAs. Circulating analyte data were combined with metadata, such as age and menopausal status, into a neural network model to classify samples as cases or controls. Forward regression with ten-fold cross-validation minimized the dimensionality of the model while maximizing linear separation between cases and controls.

Results showed that a panel of 10 miRNA delivered optimal performance when combined with protein and metadata features. The combined model improved the Receiver Operator Characteristic Area Under the Curve (ROC AUC) on the internal (AUC = 0.9; 95% CI 0.81-0.95) and external validation sets (AUC = 0.95; 95% CI 0.90-0.98) compared to miRNA alone or proteins plus metadata (without miRNA). On external validation, the combined model offered 92% sensitivity at 80% specificity overall, with 80% and 100% sensitivity for early and later-stage cancers, respectively, including 78% sensitivity for early-stage, serous ovarian cancers and 82% sensitivity for early-stage, non-serous cancers.

Dr. Todd Papas, Vice President of Research & Development at Aspira Women's Health, added, "The data are clear in showing that combining miRNA, protein and metadata improves the performance of existing technology in its ability to assess malignancy risk for women with an adnexal mass. The performance is particularly exciting for early-stage cancers and certain subtypes that have previously been more difficult to identify. Our prior research has shown that clinicians struggle to differentiate between benign andmalignant masses when they use ultrasound alone, resulting in later diagnosis or unnecessary surgicalintervention. We will now move forward with the verification and validation of the assay for our nextgeneration of non-invasive diagnostic tools for ovarian cancer to add to our current OvaSuite offerings."

Dr. Kevin Elias, the Lilli and Seth Harris Endowed Chair for Ovarian Cancer at the Cleveland Clinic, added, "These results are particularly exciting because they highlight the importance of combining different classes of molecules into next generation assays. This new assay is the most accurate test for ovarian cancer that has ever been described and marks a milestone in cancer diagnostics as the first test to incorporate both proteins and microRNAs. This new approach will ensure that more women get an accurate diagnosis prior to surgical referral." Dr. Elias continued, "As an ovarian cancer surgeon, I rely on having the most accurate preoperative assessment possible for surgical planning and counseling. This provides a better tool for patient care."

About Aspira Women's Health Inc.
Aspira Women's Health Inc. is dedicated to the discovery, development, and commercialization of noninvasive, AI-powered tests to aid in the diagnosis of gynecologic diseases.

OvaWatch® and Ova1Plus® are offered to clinicians as OvaSuite℠. Together, they provide the only comprehensive portfolio of blood tests to aid in the detection of ovarian cancer for the 1.2+ million American women diagnosed with an adnexal mass each year. OvaWatch provides a negative predictive value of 99% and is used to assess ovarian cancer risk for women where initial clinical assessment indicates the mass is indeterminate or benign, and thus surgery may be premature or unnecessary. Ova1Plus is a reflex process of two FDA-cleared tests, Ova1® and Overa®, to assess the risk of ovarian malignancy in women planned for surgery.

Our in-development test pipeline is designed to expand our ovarian cancer portfolio and addresses the tremendous need for noninvasive diagnostics for endometriosis, a debilitating disease that impacts millions of women worldwide. In ovarian cancer, our OvaMDx risk assessment is designed to combine microRNA and protein biomarkers with patient data to further enhance the sensitivity and specificity of our current tests. In endometriosis, EndoCheck℠ is the first-ever noninvasive test designed to identify endometriomas, one of the most commonly occurring forms of endometriosis. The EndoMDx test is designed to combine microRNA and protein biomarkers with patient data to identify all endometriosis.

Forward-Looking Statements
This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements regarding, among other things, the timing and completion of any products in the pipeline development and other statements that are predictive in nature. Actual results

could differ materially from those discussed due to known and unknown risks, uncertainties, and other factors. These forward-looking statements generally can be identified by the use of words such as “designed to,” “expect,” “plan,” “anticipate,” “could,” “may,” “intend,” “will,” “continue,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this press release and other factors that may cause such differences include the satisfaction of customary closing conditions related to the offering and the expected timing of the closing of the offering. These and additional risks and uncertainties are described more fully in the company’s filings with the SEC, including those factors identified as “Risk Factors” in our most recent Annual Report on Form 10-K, for the fiscal year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Aspira presently does not know, or that Aspira currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Aspira’s expectations, plans, or forecasts of future events and views as of the date of this press release. Subsequent events and developments may cause the Company’s assessments to change. However, while Aspira may elect to update these forward-looking statements at some point in the future, Aspira expressly disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Aspira’s assessments of any date after the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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