Aspira Women's Health Announces Publication of Paper Validating OvaWatch™ Algorithm in the Detection of Ovarian Cancer

Description

Paper published in the June online issue of JCO Clinical Cancer Informatics

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AUSTIN, Texas, June 16, 2022 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira"), a bio-analytical based women's health company focused on gynecologic disease, today announced the online publication of a paper validating its OvaWatch™ algorithm in the detection of ovarian cancer in the June issue of JCO Clinical Cancer Informatics.

The paper, entitled: "*Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer*," demonstrates the potential of OvaWatch in accurately assessing the risk of ovarian malignancy in patients with pelvic masses. Ovarian cancer is the deadliest gynecologic cancer, with most cases being diagnosed at late stage. Early detection of ovarian cancer is key to helping to reduce mortality; however, other current noninvasive risk assessment measures on the market vary in their usefulness.

"There is tremendous need for early ovarian cancer detection and stratification, especially for women presenting with adnexal masses. OvaWatch has been shown it can help in assessing treatment strategies, addressing many of the limitations of current biomarker-based blood tests," said Dr. Gerard Reilly, Director of Clinical Research and Innovation at Axia Women's Health and one of the lead authors of the paper. "Wider use of this non-invasive test could help in evaluating appropriate care strategies for patients presenting with a pelvic mass."

Nicole Sandford, CEO of Aspira Women's Health said, "We are very pleased to see the results of this study published in an esteemed journal. Once launched, we believe our OvaWatch risk assessment will become a valuable tool to assist physicians in determining appropriate treatment strategies for every woman with an adnexal mass, and its adoption has the potential to improve health outcomes for women with ovarian cancer."

About Aspira Women's Health Inc.
Aspira Women's Health Inc. 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 projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, research and development expenses, gross profit margin, cash flow, results of operations and financial condition; our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological diseases, including additional pelvic disease conditions such as endometriosis and, benign pelvic mass monitoring in addition to genetics risk assessment, including breast and ovarian cancer hereditary risk assessment and carrier screening; our planned business strategy and strategic business drivers and the anticipated effects thereof, including partnerships such as those based on our Aspira Synergy product, as well as other strategies, specimen collaboration and licensing; plans to expand our existing products OVA1, OVERA, OVA1plus, Aspira GenetiX and Aspira Synergy on a global level, and to launch and commercialize our new products, OvaWatch (previously OVASight), EndoCheck and OVAInherit; plans to develop new algorithms, molecular diagnostic tests, products and tools and otherwise expand our product offerings, including plans to develop a product using genetics, proteins and other modalities to assess the risk of developing cancer when carrying a pathogenic variant associated with hereditary breast and ovarian cancer that is difficult to detect through a diagnostic test; plans to establish payer coverage and secure contracts for Aspira GenetiX, OvaWatch, EndoCheck and OVAInherit separately and expand current coverage and secure contracts for OVA1; plans that would address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health; anticipated efficacy of our products, product development activities and product innovations, including our ability to improve sensitivity and specificity over traditional diagnostic biomarkers; expected competition in the markets in which we compete; plans with respect to ASPiRA LABS, including plans to expand or consolidate ASPiRA LABS' testing capabilities; expectations regarding continuing future services provided by Quest Diagnostics Incorporated; plans to develop informatics products and develop and perform laboratory developed tests ("LDTs"); FDA oversight changes of LDTs; plans to develop a race or ethnicity-specific pelvic mass risk assessment; expectations regarding existing and future collaborations and partnerships for our products, including plans to enter into decentralized arrangements for our Aspira Synergy product; plans regarding future publications; expectations regarding potential collaborations with governments, legislative bodies and advocacy groups to enhance awareness and drive policies to provide broader access to our tests; our ability to continue to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests within the United States and internationally, as applicable; our continued ability to expand and protect our intellectual property portfolio; anticipated liquidity, capital requirements, future losses and our ability to continue as a going concern; expectations regarding raising capital and the

amount of financing anticipated to be required to fund our planned operations; expectations regarding the results of our clinical research studies and our ability to recruit patients to participate in such studies; our ability to use our net operating loss carryforwards and anticipated future tax liability under U.S. federal and state income tax legislation; expected market adoption of our diagnostic tests, including OVA1, OVERA, OVA1plus, as well as our offerings of Aspira GenetiX and Aspira Synergy platform; expectations regarding our ability to launch new products we develop or license, co-market or acquire new products; expectations regarding the size of the markets for our products; expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans; plans to use each of AbbVie Inc. serum samples and ObsEva S.A. plasma samples in EndoCheck product validation studies; plans with respect to EndoCheck whether or not the FDA designates it a Breakthrough Device; expected target launch timing for OvaWatch and Endocheck; expectations regarding compliance with federal and state laws and regulations relating to billing arrangements conducted in coordination with laboratories; plans to advocate for legislation and professional society guidelines to broaden access to our products and services; and expectations regarding the impacts resulting from or attributable to the COVID-19 pandemic and actions taken to contain it. Forward-looking statements involve a number of risks and uncertainties. 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 those described in the section entitled “Risk Factors” in Aspira’s Annual Report on Form 10-K for the year ended December 31, 2020, as supplemented by the section entitled “Risk Factors” in Aspira’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. The events and circumstances reflected in Aspira’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 expressly disclaims any obligation to update, amend or clarify any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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