Aspira Women’s Health Announces the Commercial Launch of OvaWatch(SM)

Description

November 29, 2022 16:01 ET

AUSTIN, Texas, Nov. 29, 2022 (GLOBE NEWSWIRE) — Aspira Women’s Health Inc. (“Aspira”), a bio-analytical based women’s health company focused on gynecologic disease, announced the commercial launch of OvaWatch℠, a new non-invasive blood-based test for the assessment of ovarian cancer risk in women with adnexal masses. OvaWatch is part of the Company’s OvaSuite℠ portfolio of commercialized ovarian cancer risk assessment tests, including FDA-cleared assays Ova1® and Overa® (Ova1Plus®). With limited exceptions, U.S. physicians will be able to order the test for their patients starting December 1, 2022.

OvaWatch is a multivariate index assay intended to assess the risk of ovarian cancer in women with adnexal masses determined by initial clinical assessment as either indeterminate or benign. With a negative predictive value (“NPV”) of 99%, OvaWatch allows physicians to effectively rule out ovarian cancer malignancy to make more informed clinical decisions.

Utilizing a clinically validated, proprietary algorithm that incorporates seven serum biomarkers and patient features such as age and menopause status, OvaWatch provides a personalized risk assessment score and corresponding negative predictive value. A lower risk score indicates a low probability of malignancy, providing additional confidence in a clinician’s plan to manage and monitor. A higher score does not indicate the presence of cancer; rather, it may guide the clinician to consider additional clinical assessment, specialist consultation or surgery.

Nicole Sandford, CEO of Aspira said, “The launch of OvaWatch is a meaningful step forward in women’s health and a major leap for us as a company. OvaWatch significantly expands the patient population that will benefit from our OvaSuite portfolio and solidifies our position as a leader in the development of life-changing gynecologic diagnostic tools. Early provider interest indicates strong demand for OvaWatch. Our sales force is energized and committed to a successful launch, and we are confident that our in-flight reimbursement strategy will lead to broad payer coverage.”

Gerard Reilly, MD, Director of Clinical Research and Innovation at Axia Women's Health, and co-author of the OvaWatch paper entitled, "*Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer*" said, "Ovarian cancer is one of the deadliest forms of cancer because it is diagnosed most often in the late stages, leaving a tremendous unmet need for early ovarian cancer detection. Meanwhile, over 80% of surgical intervention of women with adnexal masses confirms non-malignant status, rendering significant negative health outcomes for affected women. Widespread use of OvaWatch could help physicians evaluate appropriate care strategies and stratify risk for women presenting withpelvic masses, addressing many of the limitations of current biomarker-based blood tests."

Ryan Phan, PhD, Chief Scientific Officer at Aspira added, "Physicians have expressed a strong desire for a better tool for the initial clinical assessment of ovarian cancer risk. Building on our clinically proven FDA-cleared platforms, OvaWatch supports physicians' medical management for a much larger population of women with adnexal masses, compared to the smaller subset with intermediate or high risk masses, throughout all stages of their health journey."

Dr. Phan continued, "For the first time, physicians can order a test that allows them to confidently develop a medical management plan for all adnexal masses. We believe widespread use of OvaWatch will significantly advance early-stage detection of ovarian cancer and improve the medical management of lower-risk pelvic masses."

Ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. It is the second most common gynecologic cancer in the United States, with nearly 20,000 new cases diagnosed each year. New diagnostic tools can further prevent unnecessary surgical intervention and potential loss of ovarian function.

Following the December 1, 2022 launch to all other states, Aspira expects OvaWatch to be available to New York State patients upon acceptance of its August 2022 submission.

About Aspira Women's Health Inc.

Aspira Women's Health Inc. ("Aspira") is transforming women's gynecological health with the discovery, development, and commercialization of innovative testing options for women of all races and ethnicities. OvaSuite℠ is the company's portfolio of blood-based ovarian cancer risk assessment tests designed to help healthcare providers move confidently from assessment to action for women with adnexal masses. Ova1Plus® combines Aspira's FDA-cleared products, Ova1® and OVERA®, to assess risk of ovarian malignancy in women with adnexal masses planned for surgery. OvaWatch℠, a lab-developed test with a 99% Negative Predictive Value, was designed to rule out ovarian cancer risk in patients with masses that appear benign or indeterminate based on the clinician's initial assessment. EndoCheck™, Aspira's first-of-its-kind non-invasive diagnostic test for endometriosis, is currently in development. Visit Aspira's 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 the potential effects of widespread use of OvaWatch

and the availability of OvaWatch in New York. 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, 2021, as supplemented by the section entitled “Risk Factors” in Aspira’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. These risks include, but are not limited to: our ability to continue as a going concern; our ability to comply with Nasdaq’s continued listing requirements; impacts resulting from potential changes to coverage of Ova1 through our Medicare Administrative Carrier for Ova1; impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform laboratory developed tests; our ability to comply with Food and Drug Administration (“FDA”) regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers’ ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to use our net operating loss carryforwards; our ability to use intellectual property; our ability to successfully defend our proprietary technology against third parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our laboratory operations. 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.

Investor Relations Contact:
Monique Kosse
Managing Director
LifeSci Advisors
Tel: 212-915-3820