Aspira Women's Health Announces Publication of Real-World Data Validating Use of OvaWatch for the Management of Adnexal Masses

Description

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Provides clinical validation for the use of OvaWatch℠ in the assessment of ovarian cancer risk for suspected benign or indeterminate adnexal masses

Paper published in the peer-reviewed journal, Frontiers in Medicine

AUSTIN, Texas, Jan. 06, 2023 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira"), a bio-analytical based women's health company focused on gynecologic disease, today announced its manuscript, entitled: "*Validation of deep neural network-based algorithm supporting clinical management of adnexal mass*," has been published in the prestigious peer reviewed journal, *Frontiers in Medicine.* The paper presents findings from the multi-site clinical study of the company's new assay, OvaWatch, describing real-world evidence supporting the use of OvaWatch for the clinical management of adnexal masses.

Conservative management of adnexal masses is warranted when masses are clinically characterized as benign or indeterminate. Due to the mortality risk associated with malignancy stemming from a lack of noninvasive diagnostic tools, patients and healthcare providers have often opted for a more aggressive surgical plan resulting in potentially unnecessary surgery, pain for the patient, and cost to an overburdened healthcare system.

In this multi-site clinical study, OvaWatch assay, was used to examine malignancy risk in prospective and retrospective samples of patients with an adnexal mass. In retrospective, low prevalence (N=1453, 1.5% malignancy rate) data from patients that received an independent physician assessment of benign, OvaWatch has a sensitivity of 81.8% and specificity of 87.4% for identifying a histologically confirmed malignancy, and a negative predictive value (NPV) of 99.7%. OvaWatch identified 18/22 malignancies missed by physician assessment. In the prospective real-world data set of 501 patients (2% malignancy rate), the NPV remained at 99%. Additionally, in an independent analysis set with an intentionally high malignancy rate (4%) the NPV was 88%. The consistently high NPV indicates that OvaWatch can aid clinicians in the management of women with an adnexal mass helping to add assurance that a mass has low probability of malignancy.

“The data in this study confirm the validity of the test from the previous retrospective cohorts,” said Dr.Ryan Phan, Chief Scientific and Chief Operating Officer of Aspira and the senior author of the study.“OvaWatch demonstrated a high NPV across diverse data sets and clearly showed benefit as an effectivetest supporting clinical management of suspected benign or indeterminate masses.”

Nicole Sandford, President and CEO of Aspira added, “OvaWatch is a major step forward for women facing a potential ovarian cancer diagnosis, providing them with unprecedented peace of mind and information to guide the decision of when – or even if – they should have their ovaries removed. It is gratifying to see high quality, real-world data confirming and further validating the benefit of using OvaWatch as part of an experienced physician’s treatment planning. Following the successful launch of OvaWatch last quarter, healthcare providers now have a reliable tool within our OvaSuite portfolio of blood tests for the more than 1.2 million women a year that present with a pelvic mass. We are optimistic that our products will become part of the standard physician response for those women.”

About OvaWatch
OvaWatch is a non-invasive, multivariate index assay intended for use in the initial clinical assessment of ovarian cancer risk in women with benign or indeterminate adnexal masses. With a negative predictive value (NPV) of 99%, OvaWatch allows physicians to confidently rule out ovarian cancer malignancy and choose the right treatment for the right patient at the right time.

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.

About Aspira Women’s Health Inc.
Aspira Women’s Health Inc. is transforming women’s gynecological health with the discovery, development, and commercialization of innovative testing options for women of all races and ethnicities. Ova1Plus® combines our FDA-cleared products, Ova1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses planned for surgery. EndoCheck™, Aspira’s first-of-its-kind non-invasive diagnostic test for endometriosis, is currently in development. 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 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.

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