

Aspira Women's Health Announces Three Reimbursement Milestones that Improve Patient Access to its OvaSuite SM Testing Portfolio

Description

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Expanded Medicare coverage for multi-marker testing, including Ova1Plus® and OvaWatchSM, through the 2023 Omnibus Spending Bill

Granted a new PLA Code for OvaWatch by the American Medical Association

Expanded Medicaid coverage adding another 5 states: Virginia, Alabama, Maine, Pennsylvania, and Rhode Island

AUSTIN, Texas, Dec. 27, 2022 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira"), a bio-analytical based women's health company focused on gynecologic disease, today announced that the 2023 Omnibus Spending Bill passed by Congress and awaiting President Biden's signature contains language directing the Center for Medicare & Medicaid Services (CMS) to cover multi-marker tests for ovarian cancer. The company believes all of its commercially available ovarian cancer risk assessment blood tests would fall under the recommended coverage expansion, which is expected to significantly increase access for women with pelvic masses in both Medicare and Medicare Advantage plans. It also sets the stage for commercial payers to adopt similar coverage policies.

Connecticut Rep. Rosa DeLauro, Chair of the House Appropriations Committee stated, "The fight against ovarian cancer is very personal to me. I am a more than 30-year survivor of the disease, but consider myself lucky that it was caught and treated early. The reality is that for too many women, gaps in ovarian cancer diagnostics and care still remain, and to save lives we must change this. That is why the 2023 government funding bill increases funding for research and puts ovarian cancer multimarker testing directly on the path to CMS coverage, so more women can gain access to care."

Nicole Sandford, President and CEO of Aspira, added, "Aspira is proud to have participated with clinicians, women's health advocacy groups, and most importantly, patients, to raise Congressional awareness about the need for broader access to clinically superior ovarian cancer tests. We believe this is critical for improving outcomes for women with ovarian cancer, and are firmly committed to the cause."

Valerie Palmieri, Executive Chair of Aspira's Board of Directors noted, "This was truly a patient-centric effort. Patient insights and input were included every step of the way as the bill was constructed. I want to personally acknowledge Diane Powis, the Company's Chief Spokeswoman, who advocated for this legislation right up until the day she lost her battle with ovarian cancer in December 2021. Her effort to raise awareness of this devastating disease among lawmakers was truly heroic. This is a proud day for Diane's family, and a proud day for Aspira."

Aspira also announced that it has expanded Ova1Plus Medicaid access in five states during 2022 including: Virginia, Alabama, Maine, Pennsylvania, and Rhode Island. Broadening Medicaid coverage is consistent with the Company's goal of making OvaSuite products available and affordable to all women regardless of socioeconomic status. Aspira has now secured Medicaid coverage in 27 states, representing 77% of Medicaid lives.

Lastly, the Company announced the American Medical Association (AMA) has approved a new Proprietary Laboratory Assay (PLA) code for OvaWatch, the Company's recently launched non-invasive ovarian cancer risk assessment for use in the initial clinical assessment of adnexal masses. The PLA code will be used to bill all payers effective April 1, 2023. A PLA code uniquely identifies OvaWatch, distinguishing it from other tests and allowing for a more streamlined reimbursement process.

Greg Richard, Senior Vice President of Market Access and Business Development at Aspira, stated, "Expanding insurance coverage for our OvaSuite product portfolio is critical to improved patient outcomes and to Aspira's success. Each of these three milestones – the advancement of national Medicare coverage for multi-marker tests through the Omnibus Spending Bill, expanded Medicaid coverage in five new states, and the establishment of a PLA Code for OvaWatch – are each important achievements in their own right. Taken together, though, they demonstrate powerful momentum towards achieving our reimbursement and access goals for both Ova1Plus and OvaWatch."

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.

Investor Relations Contact:

Monique Kosse
Managing Director
LifeSci Advisors, LLC
Tel: 212-915-3820