Aspira Women’s Health Receives Approval from New York State Department of Health for OvaWatch®

Description

New York State Department of Health (NYSDOH) Clinical Laboratory Evaluation (CLEP) approval allows for OvaWatch® to be marketed in New York State

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AUSTIN, Texas, Oct. 15, 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 that it has received approval from the New York State Department of Health’s (NYSDOH) Clinical Laboratory Evaluation Program (CLEP) for OvaWatch®, the Company’s non-invasive blood test for the assessment of ovarian cancer risk for women with an adnexal mass determined by initial clinical assessment as indeterminate or benign, and thus surgery may be premature or unnecessary.

NYSDOH/CLEP approval is required for all lab developed tests to ensure compliance with New York State’s clinical laboratory regulatory standards. The comprehensive review process includes an assessment of Quality Management Systems to ensure robust procedures for maintaining quality, traceability, and risk management.

“We are gratified to have secured CLEP approval for OvaWatch opening the door to one of the nation’s largest healthcare markets with over 10 million women residing in New York state,” said Nicole Sandford, CEO of Aspira Women’s Health. “Additionally, with a process that some view as equal to or more stringent than some at the Federal level, we believe that CLEP approval provides important validation of the rigorous science behind our test, strengthens our credibility in other markets, and positions us well for other regulatory pathways. I am very proud of our team and this accomplishment, and we look forward to bringing this test to the millions of women in New York state.”

About OvaWatch®
OvaWatch is the only non-invasive blood test available to assess the risk of ovarian cancer in patients with an adnexal mass initially evaluated as indeterminate or benign. With a 99% negative predictive value and longitudinal monitoring feature, OvaWatch allows physicians and patients to determine a personalized monitoring or treatment.

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 risk 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 with an adnexal mass 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. Aspira's other in-development endometriosis 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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