

ASPIRA LABs Announces In-Network Agreement with TriCare South for OVA1®

Description

[VRML_03_30_2017 ASPIRA Labs Announces TriCare South Contract](#) AUSTIN, Texas, March 30, 2017

— ASPIRA LABs, a Vermillion company (NASDAQ: VRML), today announced it has signed an in-network, contracted agreement with TriCare South for ASPIRA's U.S. FDA cleared, Centers for Medicare and Medicaid Services (CMS) covered, American College of Obstetricians and Gynecologists (ACOG) Level B recommended ovarian cancer risk assessment test, OVA1® (Multivariate Index Assay or MIA). TriCare South serves about 2.5 million beneficiaries in the states of Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Oklahoma, South Carolina, Tennessee, Texas (excluding El Paso) and Fort Campbell, Kentucky.

"We are pleased to announce our in-network, contracted TriCare South status for OVA1 (MIA)," said Valerie Palmieri, President and CEO of Vermillion, Inc. "The contract is significant as it signals the expansion of our coverage to our uniformed service members and their families. The mortality rate of ovarian cancer has not changed in 40 years, even following the introduction of the CA125 biomarker. Today, two thirds of women with ovarian cancer do not receive the appropriate treatment course. We can change this, and the time is now!"

"As previously announced, now that ACOG has included OVA1 (MIA) in its November 2016 Practice Bulletin #174 for the Evaluation and Management of Adnexal Masses, in addition to the FDA clarifying in December 2016 that its Ovarian Cancer Screening safety warning did not apply to Vermillion's two FDA cleared technologies, we believe Vermillion is well positioned to continue to expand coverage and increase access to OVA1 (MIA) for women with a pelvic mass, helping to ensure optimal care for more patients. We continue to execute on our managed care strategy in 2017, gaining momentum and positively impacting access for women nationwide."

Links to multiple clinical studies showing OVA1 (MIA)'s strong performance over CA125 for earlier and improved detection can be found on our website:

<https://aspiralsc.wpengine.com/providers/ova-1/clinical-validation-studies/>.

About Vermillion

Vermillion, Inc. is dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve [gynecologic health] outcomes for women. Vermillion, along with its prestigious scientific collaborators, discovers, develops, and delivers innovative diagnostic and technology tools that help women with serious diseases.

The company's initial in vitro diagnostic test, OVA1® (MIA), was the first FDA-cleared, protein-based In Vitro Diagnostic Multivariate Index Assay and represented a new class of software-based liquid biopsy in vitro diagnostics. In March 2016, Vermillion received FDA clearance for Overa™, a second generation OVA1 (Multivariate Index Assay 2nd Generation or MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About OVA1® and Overa™

- OVA1 (MIA) is a proprietary FDA-cleared blood test to help physicians assess the risk of ovarian

cancer prior to surgery [and as a result provide more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.

- OVA1 (MIA) now has an ACOG Level B recommendation for the Evaluation and Management of Adnexal Masses (ACOG Practice Bulletin #174, November 2016).
- The OvaCalc® proprietary algorithm combines five biomarker results into a single numerical “risk score” that stratifies patients into “higher risk” and “lower risk” when combined with clinical assessment.
- In two pivotal clinical trials, OVA1 (MIA) plus clinical impression detected 96% of all malignancies vs. 75% for clinical impression alone (CI). As a result, false negatives were reduced from 25% for CI, to 4% with OVA1 (MIA) plus CI, a reduction of 83%.
- In a study focused on early-stage cancer detection, 31% of cases were missed by clinical impression alone. This was reduced to 5% when OVA1 (MIA) was added to clinical impression, a reduction of 85%. [1]
- Overa (MIA2G), cleared by FDA in March 2016, measures the levels of five proteins found in the blood and then uses a second-generation OvaCalc® algorithm to stratify risk. A woman’s risk of cancer is measured by using a 0-10 scale with a single cut-off point of 5 eliminating the ambiguity in determining menopausal status. A high Overa score is not a diagnosis of cancer, rather it indicates an increased risk of malignancy when used as intended.
- **PRECAUTION:** OVA1® and Overa tests should not be used without an independent clinical/radiological evaluation and are not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1® or Overa carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined in the Private Litigation Reform Act of 1995 that involve significant risks and uncertainties including statements regarding Vermillion’s position to expand coverage for OVA1 (MIA). 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. The forward-looking statements contained in this press release are based on Vermillion’s expectations as of the date of this press release. A variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements, including changes to interpretations of existing laws and regulations and other factors that are described in Vermillion’s Form 10-K for the year ended December 31, 2015 and Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission. Vermillion expressly disclaims any obligation to update, amend or clarify any forward-looking statements to reflect events, new information or circumstances occurring after the date of this press release, except as required by law.

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[1] Bristow RE, Smith A, Zhang Z, Chan DW, Crutcher G, Fung ET, et al. Ovarian malignancy risk

stratification of the adnexal mass using a multivariate index assay. *Gynecol Oncol* 2013 Feb; 128(2):252-9.
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