

Aspira Labs Expands Coverage For Ova1® In California

Description

AUSTIN, Texas — ASPiRA LABS, a Vermillion company (NASDAQ: VRML), today announced an agreement has been reached with Sacramento-based Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation) for coverage of OVA1, Vermillion's ovarian cancer risk assessment test commercialized by ASPiRA LABS.

"We are pleased to announce OVA1 coverage expansion with Gould Medical Foundation, a California network provider," said Valerie Palmieri, President and CEO of Vermillion, Inc. "Reaching more women with our technology is our mission. Providing testing that can improve outcomes in ovarian cancer, where the mortality rate has not changed in 40 years, is our passion. OVA1, compared to modified ACOG criteria, aids in the detection of all ovarian cancer stages, including stage 1 and 2 which may help identify the most suitable provider for optimal patient care. Expanding access to OVA1 is our goal, so that we can serve women at an elevated risk for ovarian cancer. These agreements with Gould Medical Foundation are part of our campaign to pursue managed care coverage agreements throughout 2016. Our focus is to continue to expand OVA1 test adoption, to build our data repository further and to expand our clinical studies in order to demonstrate the 'total cost of care' benefit of OVA1 to healthcare systems."

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[®], 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 test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About OVA1®

- OVA1 is a proprietary FDA-cleared blood test designed to help physicians assess the risk of ovarian cancer prior to surgery, facilitating more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.
- 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 plus clinical impression detected 96% of all malignancies vs. 75% for clinical impression alone. As a result, false negatives were reduced from 25% for clinical impression alone, to 4% with OVA1 plus clinical impression, a reduction of 83%.
- In a study focused on early-stage ovarian cancer detection, 31% of cases were missed by clinical impression alone. This was reduced to 5% when OVA1 was added to clinical impression, a reduction



of 85%.

 OVA1 has shown clinical utility in increasing the rate of referrals of malignant adnexal masses to gynecologic oncologists. The increased involvement of specialists may lead to increased National Comprehensive Cancer Network-adherent cancer care, which is associated with improved cancer outcomes, including overall survival. In a study focused on specialist involvement in ovarian cancer treatment, 94% of patients with an elevated-risk OVA1 result who had primary ovarian malignancies were appropriately referred to a gynecologic oncologist.