Vermillion Announces Publication of Study Demonstrating 100% Sensitivity and Negative Predictive Value of OVA1 and Symptomatology Combination

AUSTIN, Texas, March 29, 2017 -- Vermillion (NASDAQ: VRML) announced today the acceptance for publication of the original research titled, "Evaluation of a Validated Biomarker Test in Combination With a Symptom Index to Predict Ovarian Malignancy," by Renata R. Urban, MD, Alan Smith, MS, Kathy Agnew, Vinicius Bonato, PhD, and Barbara A. Goff, MD, in the International Journal of Gynecological Cancer.

Ovarian cancer is expected to affect over 22,000 U.S. women in 2017 [(1)], greater than 200,000 women globally [(2)], and has the worst survival rate of all gynecological cancers, with a 5 year survival of less than 50% [(1)]. Earlier detection and proper care pathways increase the chance of survival and patient outcomes [(3-5)], which has been the primary mission of Vermillion/ ASPiRA Labs since OVA1 (MIA) was first launched in 2010. In a seminal study published in 2009, [(6)] Dr. Barbara Goff and colleagues defined a set of symptoms that were useful in identifying women with ovarian cancer, and developed a symptom index (SI) relating these symptoms to the likelihood and severity of the disease and suggested that symptoms may facilitate earlier detection. In a 2016 study performed with 218 patients who presented with pelvic masses, the combination of SI and OVA1 (MIA) showed a sensitivity to detect primary ovarian malignancy of 100%, detecting both early and late stage cancers better than either SI or OVA1 (MIA) alone. Additionally, the negative predictive value of SI and OVA1 combined was also 100%, indicating that all women that tested negative for both tests were certain not to have a primary ovarian malignancy [(7)].

The appropriate referral of patients who are high risk for ovarian cancer is necessary for optimal outcomes; however, referral of benign cases can increase wait times for a specialist visit and often, if unnecessary, can increase anxiety and other burdens for the patient. Using all preoperative information available to the clinician, which includes symptoms, physical exam, ultrasound findings, and OVA1 (MIA) results can facilitate the appropriate triage of patients with a pelvic mass either to the Gynecologic Oncologist or to remain with their OB/Gyn provider for care and surgery.

"Vermillion is dedicated to working towards improving the lives and outcomes of women with ovarian cancer, and we are very encouraged by the results of this latest study," stated Marra Francis, MD, FACOG, CMO of Vermillion.

OVA1 (MIA) is now considered a Level B Recommendation by ACOG [(8)]. Based on its support by ACOG, NCCN update and SGO positive position statement, OVA1 (MIA) can be the physician's first choice in biomarker panels to best triage their pelvic masses to the most appropriate care pathway. There is no other comparable technology on the market today.

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 Multivariate Index Assay 2nd Generation (MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.vermillion.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.

- 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%.

- 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.

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