Vermillion Announces Publication of New Study Demonstrating Overa's Greater Sensitivity in Detecting Ovarian Cancer Compared with ROMA, HE4 + CA125, and CA125 Alone

Description

Highest Performing Early Stage Ovarian Cancer Risk Assessment Available Today

Link to the full press release here

AUSTIN, Texas, July 16, 2019 – Vermillion, Inc. (Nasdaq: VRML), a bioanalytical-based women's health company focused on gynecologic disease, today announced publication of a paper entitled: "Clinical Performance Comparison of Two In-Vitro Diagnostic Multivariate Index Assays (IVDMIAs) for Presurgical Assessment for Ovarian Cancer Risk" in the journal Advanced Therapeutics (Shulman et al. Adv Ther. July 2019). The study of 993 patients with 245 malignancies shows that Vermillion's second-generation multivariate index assay, Overa® (MIA2G), had superior sensitivity to the current standards of care, Risk of Malignancy Algorithm (ROMA) and CA125, in detecting ovarian cancer, and the lowest false-negative rate incorrectly characterizing ovarian malignancy risk.

"These findings advance our ability to detect ovarian malignancy and provide clinicians with reliable tools to screen adnexal masses." said Lee Shulman, M.D., principal investigator and Anna Lapham Professor of Obstetrics and Gynecology, Feinberg School of Medicine, Northwestern University. "The ability to better detect disease while reducing the number of missed cancer cases, is critical for improving outcomes for women with adnexal masses.

This is the first study published with respect to Overa since it received FDA approval. Key findings from the study include:

Overa exhibited a statistically significant higher sensitivity (91%; 95%CI, 86.8% – 94.0%) of malignancy detection than either ROMA (79.2%: 95%CI, 73.7% – 83.8%) or CA125 (71%; 95%CI, 65.0% – 76.30%), with the current ACOG guidance cutoff of 200 U/ml

- Overa also outperformed CA125 in detection of combined early-stage (I and II) cancer with a sensitivity of 90.5% (95%CI, 82.3% – 95.1%) for Overa and a sensitivity of 63.1% (95%CI, 52.4% – 72.6%) for CA125. Overa sensitivity also tended to outperform ROMA (76.2%; 95%CI, 66.1% – 84.0%) in the detection of combined early-stage (I and II) cancer.
- Overa also tended to exhibit higher sensitivity than CA 125 and ROMA regardless of cancer type (epithelial, non-epithelial, low malignancy potential, metastatic, and non-metastatic)
- Overa exhibited a significantly higher non-epithelial cancer sensitivity of 75% compared with 50.0% for ROMA, and 37.5% for CA125. This gap is significant as non- epithelial cancers are more prevalent in disparate populations.
- Out of the 245 malignancies, Overa exhibited the lowest rate of false negatives (8.9%) compared with

CA125 (28.9%) or ROMA (20.8%)
- As compared to CA125 and ROMA, Overa exhibited the highest sensitivity according to menopausal status. Overa also had identical sensitivity for pre- and post-menopause

“The findings from this study further establish that early-stage risk assessment of ovarian cancer is possible with our OVA technology,” said Valerie Palmieri, President and Chief Executive Officer of Vermillion, Inc. “The greatest barrier for women to obtain the proper treatment has been the lack of early detection tools, with the OVA technology the early stage risk assessment gap has finally been filled. Vermillion is committed to improving the pre-surgical pelvic mass assessment, so all stages, ages, and ethnicities can access the right treatment at the right time.”

Vermillion’s proprietary technologies, OVA1 and Overa, are FDA-cleared blood tests to evaluate cancer risk in women presenting with a pelvic mass, thus helping healthcare providers and women assess risk for malignancy prior to surgery.

About Vermillion, Inc.

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.

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