Vermillion Announces Two Independent Publications Showing OVA1® (MIA- Multivariate Index Assay) Demonstrates Improved Ovarian Malignancy Risk Detection in African-American Women

Description

Milestone data announced during Ovarian Cancer Awareness Month, which demonstrates OVA1's superior sensitivity of ovarian cancer risk detection in both Caucasian and African American women versus other testing options, CA125 or ROMA

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AUSTIN, Texas, September 4, 2019 – Vermillion, Inc. (Nasdaq: VRML), a bioanalytical-based women's health company focused on gynecologic disease, today announced the publication of two independent studies demonstrating that OVA1® (Blood Multivariate Index Assay (MIA) for Ovarian Cancer Risk Assessment) improves ovarian cancer risk detection in women compared to alternative technology, such as CA125 and CA125 & HE4 (Risk of Malignancy Algorithm ROMA). With more than 80% of ovarian cancer being diagnosed in late stages (1), and specifically the mission for Ovarian Cancer Awareness Month, of earlier recognition of symptoms and earlier detection. (2)

The studies specifically demonstrate that OVA1 is markedly more sensitive in ovarian cancer detection in African-American women 79.2% for OVA1, vs. 33.3% compared to CA1253, and 79.1% v. 54.5% compared to CA125 plus HE4 (Risk of Malignancy Algorithm ROMA), when using the American College of Obstetricians and Gynecologists (ACOG) cutoff >200 CA125 U/ml3 for premenopausal women. In addition, even applying a more conservative 2007 cutoff for premenopausal women (CA125 >67 U/ml, Dearking 2007)4, OVA1® still outperformed CA125 whose sensitivity was only 62.5%.

"Recent studies have shown that African American women have lower CA125 levels than other ethnicities which could lead to under-diagnosis of cancer in that population. Our results from the two new studies demonstrate that OVA1 is clearly superior to CA-125, as well as to ROMA, in ovarian cancer risk detection for women with pelvic masses, particularly in African American women" said Charles Dunton, M.D., Global Medical Director of Vermillion, and lead author. "By giving more women greater access to a better risk detection method, we can help correct the disparity in care offered to African-American women, who generally have poorer survival rates from ovarian cancer and currently face a greater risk of cancer not being detected."

Key takeaways from the studies:

“Multivariate Index Assay Outperforms CA125 in Detection of Ovarian Malignancy in African American Women” authored by Dunton et al was published in Future Oncology; Published Online: Aug 2019; https://doi.org/10.2217/fon-2019-0310

- OVA1 (MIA) in African American women is more sensitive than CA125; 79.2% v 33.3% (2007 ACOG)3 v 62.5% (2007 Dearking)4
- OVA1 (MIA) in Caucasian women is more sensitive than CA125, 93.2% v 80.4%

“Multivariate Index Assay is Superior to CA125 and HE4 Testing in Detection of Ovarian Malignancy in African American Women” authored by Dunton et al, was published in Biomarkers in Cancer 11:1-4, 2019

- OVA1(MIA) in African American women is more sensitive than ROMA: 79.1% v 54.5%
- OVA1(MIA) in Caucasian women is more sensitive than ROMA: 93.2% v 82.9%

“This is very interesting data. This sort of research is critical to understand tumor marker and OVA1 (MIA) differences in race and ethnicity”, said Barbara Goff, MD. Professor and Chair of Obstetrics and Gynecology and affiliated researcher at the Fred Hutchinson Cancer Research Center, University of Washington School of Medicine. “It is so critically important to investigate the sensitivity of such detection methods based on the inherent differences in individual populations. This preliminary research points to a substantial step in the right direction.”

OVA1® is an FDA-cleared and ACOG endorsed blood test offered via ASPIRA Labs®, Vermillion’s wholly-owned subsidiary. OVA1® proactively assesses the risk of ovarian malignancy from a simple blood test, as a pre-operative biopsy is not medically appropriate. Clinically, OVA1® objectively guides the patient treatment care plan for low risk and high-risk pelvic mass patients.

“Disparity in care continues to be a major global problem, and particularly for cancer risk detection and treatment for underserved women,” said Valerie Palmieri, President, and CEO of Vermillion, Inc. “We are proud that OVA1® is demonstrated to accurately identify more patients, especially African-American women, and help ensure that they get the proper treatment. We will continue to work to support the goals of Ovarian Cancer Awareness Month and give ALL women of every socioeconomic background access to the best possible methods of cancer risk detection.”

Visit www.aspirawh.com for more information.

1 https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html
2 http://ovarian.org/page-not-found/508-ovarian-cancer-awareness-month
3 Practice Bulletin No. 174: Evaluation and Management of Adnexal Masses. Obstet. Gynecol. 128(5), e210–e226 (2016).
4 Dearking AC, Aletti GD, McGree ME et al. How relevant are ACOG and SGO guidelines for referral of adnexal mass? Obstet. Gynecol. 110(4), 841–848 (2007).