

Vermillion Announces Acceptance of Publication: Ethnic Disparity Data Showing OVA1 (MIA) Superiority over CA125 and HE4 in Detecting Ovarian Cancer Risk

Description

Data showing detection improvements across all populations, with marked improvement in detecting ovarian malignancy risk in the African American population
Findings to be published in Biomarkers in Cancer

AUSTIN, Texas, May 13, 2019 – Vermillion, Inc. (Nasdaq: VRML), a bioanalytical-based women's health company focused on gynecologic disease, today announced acceptance of a paper entitled: "*Multivariate Index Assay is Superior to CA125 and HE4 Testing in Detection of Ovarian Malignancy in African American Women*" in the journal [Biomarkers in Cancer](#). The paper reviews data from previous prospective studies from ASPIRA LABS®, Vermillion's wholly owned subsidiary, that show the Company's OVA1[®] multivariate index assay had superior sensitivity to CA125 and HE4 (Risk of Malignancy Algorithm ROMA) in detecting ovarian malignancy risk in all populations, with marked improvement in detecting ovarian cancer in the [African American population](#).

"These findings are important in helping clinicians select the most effective testing method when looking to detect risk of ovarian malignancy, particularly in the African American population," stated Charles Dunton, M.D., Global Medical Director of Vermillion. "It is well known that African American women have poorer survival from ovarian cancer and the ability to better detect disease in this population should improve outcomes. Utilization of OVA1 should help identify more patients, especially African American women, who should be referred for specialty care, that are missed by CA125 and HE4. We believe this could help close a gap in care in this population."

The Company initiated the analysis after the publication of four independent articles showed that African American and non-Caucasian women have lower CA125 levels than Caucasian women. CA125, HE4 and Risk of Malignancy Algorithm (ROMA) are testing options for evaluating women with pelvic masses and determining clinical management. With lower CA125 levels in African American and non-Caucasian populations, the CA125 test has the potential to miss identifying ovarian malignancy risk in the non-Caucasian populations. The paper revealed that OVA1 detected ovarian malignancies in African American women 79.1% of the time compared to 54.5% of the time when using CA125 and HE4 tests. [OVA1](#) was superior in Caucasian women, as well, detecting ovarian cancer 93.2% of the time compared to 82.9% of the time using CA125 and HE4.

“We have finally reached the moment, to deliver an FDA cleared and guideline supported technology that demonstrates the ability to detect risk of cancer more effectively than the existing 38-year-old CA125 technology as well as CA125 plus HE4 (Risk of Malignancy Algorithm ROMA). It is now time that all women of every socioeconomic background receive the best care possible and we are proud and excited to make that happen”, stated Valerie Palmieri, President and CEO.

OVA1 is FDA-cleared, [American College of Obstetrician and Gynecologist](#) (ACOG) endorsed and has the highest risk detection rate for all ages, ethnicities, stages and all types of ovarian cancer. OVA1 is intended to detect risk of malignancy, and to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in monitoring response to therapy.

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