Vermillion and ASPiRA LABs Applaud the FDA's Position on Ovarian Cancer Screening

Description

AUSTIN, Texas — ASPiRA LABs, a Vermillion company (NASDAQ:VRML), today announced its support for the recent US Food and Drug Administration (FDA) safety communication which recommends against the use of any screening tests for ovarian cancer.

Earlier this week, the FDA announced that it is alerting women about the risks associated with the use of tests being marketed as ovarian cancer screening tests. The Agency stated that it is especially concerned about delaying effective preventive treatments for women who show no symptoms, but who are still at increased risk for developing ovarian cancer.

As the medical community knows, ASPiRA LABs' FDA cleared technologies, OVA1® and Overa™, are NOT screening tests. OVA1/Overa are FDA cleared technologies to assess risk of ovarian cancer malignancy for women who present with a pelvic mass and are planned for surgery.

Vermillion is pleased that the FDA recognizes that there is no FDA cleared screening for ovarian cancer. The FDA communication also stated "Using unproven ovarian cancer screening tests also may be harmful for women with increased risk for developing ovarian cancer." There were other concerns, specifically to technology such as the ROCA Ca125 test, outlined in the FDA statement:

"Some women may receive test results that suggest ovarian cancer even though no cancer is present (a false-positive). These women may undergo additional medical tests and/or unnecessary surgery, and may experience complications related to both. Or, test results may not show ovarian cancer even though cancer is present (a false-negative), which may lead women to delay or not seek surgery or other treatments for ovarian cancer."

False-positive or false-negative test results can lead to incorrect treatment decisions by providers in their management of the risk of ovarian cancer.

"We believe this clarity around the use of non-FDA cleared tests for ovarian cancer screening, demonstrates the need to manage high risk pelvic mass patients at the onset with our FDA cleared technology," stated Valerie Palmieri, President and CEO of Vermillion/ASPiRA LABs. "No technology exists today to support screening, but we believe that our technology is the best available to assess risk, optimally manage patients, and lower overall healthcare costs. The mortality rate for ovarian cancer has not improved in 40 years and our goal is to change that statistic."

The power of OVA1 /Overa is the negative predictive value. The majority of pelvic masses are benign and Vermillion's data shows that 97% of the patients that have low risk OVA1/Overa results actually do have a benign mass. Thus, the results give doctors and their low risk patients "peace of mind" as they make their surgical decisions AND ensure that the elevated risk patients are referred to a gynecologic oncologist in the most efficient way. Unless an effective screening test becomes available, the OVA1 and Overa blood tests are the only FDA cleared diagnostic that can provide a cancer risk assessment for all stages, all ages and all types of ovarian cancer.

ASPiRA LABs welcomes comments on this position statement and other women's health issues. Please

contact the company at marketing@aspirawh.com.

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® and Overa™

- 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.
- Overa, cleared by the FDA in March 2016, measures the levels of five proteins found in the blood and then uses a second-generation algorithm, incorporated into the OvaCalc® software, 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.

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