Vermillion and ASPiRA LABS' Announce Receipt of Formal FDA Clarification Regarding Ovarian Cancer Screening Alert

Description

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AUSTIN, Texas, January 4, 2017, Vermillion (NASDAQ: VRML) and ASPiRA LABS, a Vermillion company, today announced the receipt of an FDA Clarification Letter regarding OVA1 (MIA) and Overa (MIA2G). This letter is in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women.
In order to avoid any confusion as well as to document the FDA position on OVA1 (MIA) and Overa (MIA2G), Jeffrey Shuren, M.D, J.D, Director: Center for Devices and Radiological Health at the FDA, sent a letter to Vermillion, dated December 21, 2016. In the letter, Dr. Shuren stated: "We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 (MIA) and Overa (MIA2G), which are not screening tests for ovarian cancer."

"FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same-to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass."

Valerie Palmieri, President and CEO of Vermillion stated, "Based on the FDA Clarification, along with our 'new' Level B status in the latest ACOG Guidelines on the Adnexal Mass[4] as well as NCCN support, we believe we have the strongest clinical solution for women and their physicians to assess a patient's risk of ovarian cancer when they present with a pelvic mass."

Vermillion is dedicated to the fight to improve outcomes for women diagnosed with ovarian cancer by identifying the disease at earlier stages and facilitating their transfer of care to a specialist sooner, which is well known to improve patient outcomes and survival[1-3]. The Company markets the only FDA cleared technology available today to identify risk of ovarian malignancy for all ages, all stages and all ovarian cancer types.

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.1. Chan JK, Kapp DS, Shin JY, et al. Influence of the gynecologic oncologist on the survival of ovarian cancer patients. Obstet Gynecol. 2007;109:1342Y1350.3. Vernooij F,Heintz P,Witteveen E,etal.The outcomes of ovarian cancer treatment are better when provided by gynecologic oncologists and in specialized hospitals: a systematic review. Gynecol Oncol. 2007;105:801Y812
- 4. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Management of adnexal masses. Obstet Gynecol. 2016; 128: e210-26.
- 2. Engelen MJ ,Kos HE,Willemse PH,etal. Surgery by consultant gynecologic oncologists improves survival in patients with ovarian carcinoma. Cancer. 2006;106:589Y598.