Vermillion, Inc. and Einstein Medical Center Philadelphia Announce the First Patient Enrolled in Prospective National Clinical Study of Ovarian Cancer Risk Detection Methods in African American Women

Description

Study evaluates the differences in sensitivity of ovarian cancer risk detection between OVA1® Plus and CA125

For a link to a pdf of the press release please click here

AUSTIN, Texas and Philadelphia, Pennsylvania; December 17, 2019 – Vermillion, Inc. (Nasdaq: VRML), a bioanalytical-based women's health company focused on gynecologic disease and Einstein Medical Center, the largest independent academic medical center in Philadelphia, today announced the first patient enrolled in a study that compares OVA1® to CA125 assay for detection of ovarian cancer risk in African American women.

The study will enroll over 200 prospective African American women with adnexal masses. Ovarian cancer risk will be assessed by both CA125 and OVA1® Plus. The primary objective is to determine the differences in sensitivity and accuracy of cancer risk detection between the testing methodologies. The study is to be expanded to women of varying ethnic backgrounds as well.

"African American women have lower incidence of ovarian cancer than Caucasian women, yet a higher all-cause mortality rate," said Lead Investigator Kate Stampler, D.O., Department of Obstetrics and Gynecology at Einstein Medical Center Philadelphia. "Recent evidence demonstrates that they also have lower levels of CA125 that could lead to underdiagnosis."

Recently published studies demonstrate that OVA1® has greater sensitivity in detecting ovarian cancer across multiple ethnicities and technologies including CA125 and ROMA:

- OVA1® in African American women is 2.38-times more sensitive than CA125: 79.2% v 33.3%[1]
- OVA1® in African American women is 1.45-times more sensitive than ROMA: 79.1% v 54.5%[2]

- OVA1® in Caucasian women is more sensitive than CA125: 93.2% v 74.4%[1]
- OVA1® in Caucasian women is more sensitive than ROMA: 93.2% v 82.9%[2]

"This study should confirm that OVA1® provides more sensitive risk detection in African American women. It may also define differences in sensitivity amongst various ethnicities and races," said Charles Dunton, MD, Global Medical Director, Vermillion. "This study can help address the disparities in diagnosis and outcomes of ovarian cancer in African American women."

OVA1® is an FDA-cleared and ACOG-endorsed blood test offered via ASPiRA Labs. OVA1® proactively

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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.

About Einstein Healthcare Network

Einstein Healthcare Network is a healthcare system with approximately 1,000 beds and more than 8,700 employees serving the communities of Philadelphia and Montgomery County, Pa. The Network is made up of three acute care hospitals including Einstein Medical Center Philadelphia, the largest independent academic medical center in the Philadelphia region training over 3,500 health professional students each year with 400 residents in more than 30 accredited programs; Einstein Medical Center Elkins Park; and Einstein Medical Center Montgomery. The Network also includes MossRehab, consistently ranked by U.S. News & World Report as a top rehabilitation hospital in the nation; Willowcrest, named by U.S. News & World Report as one of the best nursing homes for short-term rehabilitation care in Philadelphia; outpatient care centers; and a network of more than 900 primary care physicians and specialists throughout the region. For more information, visit www.einstein.edu or call 1-800-EINSTEIN.

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