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Description

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AUSTIN, Texas, November 8,2018 — Vermillion, Inc. (NASDAQ: VRML), a bioanalytical-based women's health company focused on gynecologic disease, today announced a study agreement and coverage with Clalit Health Services in Israel. The study is intended to validate on the local Israeli population: 1) Vermillion's first generation, U.S. FDA cleared, American College of Obstetricians and Gynecologists (ACOG) recommended ovarian cancer risk assessment test, OVA1 (MIA); 2) Vermillion's second generation U.S. FDA cleared OVERA®(MIA2G) test; and 3) Vermillion's recently launched OVA1®+ which is a reflex process that provides both of these FDA-cleared test results on one informatic report. Clalit Health Services is Israel's largest HMO and healthcare provider, with approximately 3.8 million insured members or about half of the insured Israeli population.

In Israel, nearly half of the 6.5 million Jewish population is of Ashkenazi Jewish descent. The Ashkenazi Jewish population has about a 1 in 50 (or 2%) chance of inheriting the *BRCA 1/2*mutation. The lifetime ovarian cancer risk for women with a *BRCA1* mutation is estimated to be between 35% and 70%, and for women with a *BRCA2*mutation, the risk has been estimated to be between 10% and 30% by age 70. Useof OVA1®(MIA), OVERA®(MIA2G) and OVA1®+, will be studied by Clalit in the local Israeli population to determine if earlier stage disease can be diagnosed and if the time to surgical treatment can be expedited for improved surgical outcomes for patients with an adnexal mass.

Additionally, Clalit is now covering Vermillion's OVA1®(MIA) test as part of "**Clalit Mushlam Coverage"** for its providers via ProGenetics, Vermillion's Israeli distributor. Clalit Mushlam provides wider access to medical services that members can purchase above and beyond the minimum level of medical services provided under Israel's National Health Insurance Law.

"We are very excited about the comprehensive study and coverage of OVA1®, OVERA®and OVA1®+ in this high risk population and are pleased to work with Clalit Health Services in providing the best in class technology for its members," said Valerie Palmieri, President and CEO of Vermillion, Inc.

About Clalit

Clalit Health Services is Israeli's largest HMO and healthcare provider, with some 3.8 million insured members from every ethnic group and every walk of life in Israel. Clalit is proudly one of the most progressive public health associations in the world, with humanitarian tenets still remaining the cornerstone of its philosophy and practice. Through its 14 hospitals and more than 1,200 primary and specialized clinics, Clalit provides comprehensive health insurance and highly advanced medical care to the majority of Israel's population. It is also the only health fund with a countrywide network of state-of-the-art pharmacies, dental clinics, laboratories, diagnostic imaging and specialist centers. Clalit doctors and hospital specialists cooperate to provide a broad medical-social perspective for the care of the individual, the family and the

community.

About ProGenetics

ProGenetics is an innovative company focused on personalized medicine. Founded in 2015, it has rapidly grown, offering advanced diagnostic services in the fields of oncology, gynecology and urology. In 2017 ProGenetics joined the BATM group, a multinational leading provider of real-time technologies for networking solutions and medical laboratory systems that is traded on the London Stock Exchange (LSE) and active in the U.S. and Europe. Together with BATM, ProGenetics is now expanding its services to Eastern Europe and spreading the future of personalized diagnostics around the globe.

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®(MIA), 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®(MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About OVA1® (MIA) and OVERA®(MIA2G)

- OVA1®(MIA) 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.
- OVA1®(MIA) has an ACOG Level B recommendation for the Evaluation and Management of Adnexal Masses (ACOG Practice Bulletin #174, November 2016).
- The OvaCalc® proprietary algorithm combines five biomarker results into a single numerical "risk score" that stratifies patients into "elevated risk" and "low risk" when combined with clinical assessment.
- In two pivotal clinical trials, OVA1®(MIA) plus clinical assessment detected 94% of all malignancies vs. only 77% for CA125 plus clinical assessment,[1]and OVA1®(MIA) plus clinical assessment detected 95.3% of all malignancies vs. only 80% for CA125 plus clinical assessment.[2]
- In a study focused on early-stage ovarian cancer detection, 31% of cases were missed by clinical impressionalone. This was reduced to 5% when OVA1®(MIA) was added to clinical impression, a reduction of 85%.[3]
- OVERA®(MIA2G) 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.
- OVA1®(MIA) 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 adherence to National Comprehensive Cancer Network guidelines that include surgical treatment by

a gynecologic oncologist, 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®(MIA) result who had primary ovarian malignancies were appropriately referred to a gynecologic oncologist.[4]

- 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**.**

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[1]Ware Miller R, Smith A, DeSimone CP, Seamon L, Goodrich S, Podzielinski I, et al. Performance of the American College of Obstetricians and Gynecologists' ovarian tumor referral guidelines with an index assay. Obstet Gynecol 2011 Jun; 117(6):1298-306.
[2]Longoria TC, Ueland FR, Zhang Z, Chan DW, Smith A, Fung ET, et al. Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. Am J Obstet Gynecol 2014 Jan; 210(1):78.e1-9.
[3]Bristow RE, Smith A, Zhang Z, Chan DW, Crutcher G, Fung ET, et al. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecol Oncol 2013 Feb; 128(2):252-9.
[4]Eskander RN, Carpenter BA, Wu HG, Wolf JK. The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients. Curr Med Res Opin 2016 Jun; 32(6):1161-5.