OVA1 Improves Ovarian Cancer Detection Over CA 125 Blood Test and Clinical Assessment

May 24, 2011

Second study in Obstetrics & Gynecology showcases OVA1's role in evaluating women with an ovarian mass

MADISON, N.J. and AUSTIN, Texas, May 24, 2011 /PRNewswire via COMTEX/ -- A paper published in the June issue of *Obstetrics & Gynecology* demonstrated that adding OVA1 to a physician's preoperative assessment of a woman's ovarian mass would identify more ovarian cancers than a physician's preoperative assessment alone. The study is the second published online this month in the journal, which is the official publication of the American College of Obstetricians and Gynecologists (ACOG), to show OVA1's value over the CA 125 test in evaluating women for the likelihood of ovarian cancer prior to surgery.

OVA1 is the first test cleared by the U.S. Food and Drug Administration (FDA) for aiding in the pre-surgical evaluation of a woman's ovarian mass for cancer. An estimated 300,000 surgeries are performed on women with an ovarian mass each year. Vermillion, Inc. (Nasdaq: VRML), a molecular diagnostics company, developed OVA1, and Quest Diagnostics Incorporated (NYSE: DGX), the world's leading diagnostic testing company, offers OVA1 testing services in the United States and India. Quest Diagnostics and Vermillion both participated in the study and Vermillion also helped fund the study.

In the manuscript "Effectiveness of a Multivariate Index Assay in the Preoperative Assessment of Ovarian Tumors," physician assessment and the use of OVA1 correctly identified 70% of malignancies missed by physician assessment among gynecologists and other non-gynecologic oncologists, and 95% of malignancies missed by physician assessment among gynecologic oncologists. OVA1 also detected 76% of malignancies that would have been missed by CA 125 using ACOG-recommended guidelines.

"Physician impression, which typically incorporates traditional methods such as imaging, physical examination, and CA 125, does not do an adequate job of identifying early stage ovarian cancer," states Dr. Frederick Ueland, author of the paper and principal investigator of the OVA1 clinical trial. "In this study, OVA1 identified 98% of early stage epithelial ovarian cancers compared to 68% identified by CA 125. Furthermore, OVA1 identified 93% of premenopausal early stage cancers compared to only 36% identified by CA 125."

The OVA1 test incorrectly identified non-cancerous masses about twice as often as CA 125 or clinical assessment. A higher false positive rate may increase patient distress and the number of surgeries that specialists unnecessarily perform. Dr. Ueland noted in the study that in current clinical practice only 12% to 40% of patients referred to gynecologic oncologists have malignant disease, and therefore the OVA1 false positive rate is in line with real-world referral patterns.

Of more importance is the decreased number of false negatives or undetected cancers when OVA1 is added to a physician's assessment, which is reduced from 28% to 8% in non-gynecologic oncologist assessment and from 21% to 1% in gynecologic oncologist assessment. This translates into potentially more cancers being referred to a gynecologic oncologist for initial surgery. The investigators go on to say, "hopefully, earlier referral of patients with ovarian cancer will improve survival and reduce the number of required re-operation."

The study manuscript follows online publication on May 9, 2011 in *Obstetrics & Gynecology* that suggested OVA1 may be appropriate in place of CA 125 in ACOG referral guidelines for women under evaluation for an ovarian mass ("Performance of the American College of Obstetricians and Gynecologists' Ovarian Tumor Referral Guidelines With a Multivariate Index Assay," by Dr. Rachel Miller.) The two articles are based on data from the same study and both are published in the June 2011 print edition.

About OVA1

OVA1 is the first test cleared by FDA for aiding in the pre-surgical evaluation of a woman's ovarian mass for cancer, and also is the first protein-based In Vitro Diagnostic Multi-Variate Index Assays (IVDMIA), a new class of state of the art software-based diagnostics. The test utilizes five well-established biomarkers -- Transthyretin (TT or prealbumin), Apolipoprotein A-1 (Apo A-1), beta2-Microglobulin (beta2M), Transferrin (Tfr) and Cancer Antigen 125 (CA 125 II) -- and proprietary software to determine the likelihood of malignancy in women with ovarian mass for whom surgery is planned. OVA1 is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist.

It is an aid to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The test should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the OVA1 Test carries the risk of unnecessary testing, surgery, and/or delayed diagnosis. Additional product information can be found at http://www.ova-1.com/.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at http://www.questdiagnostics.com/.

About Vermillion, Inc.

Vermillion, Inc. is dedicated to the development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Vermillion, along with its prestigious scientific collaborators, has diagnostic programs in oncology, cardiology and women's health. Additional company information can be found at http://www.vermillion.com/.

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