U.S. Food and Drug Administration Clears Vermillion's OVA1(TM) Test to Determine Likelihood of Ovarian Cancer in Women with Pelvic Mass

September 11, 2009

First lab test that can indicate ovarian cancer prior to biopsy or exploratory surgery

MADISON, N.J. and FREMONT, Calif., Sept. 11 /PRNewswire-FirstCall/ -- The U.S. Food and Drug Administration (FDA) today cleared the OVA1(TM) Test, the first blood test that, prior to surgery, can help physicians determine if a woman is at risk for a malignant pelvic mass. OVA1 is the first FDA-cleared laboratory test that can indicate the likelihood of ovarian cancer with high sensitivity prior to biopsy or exploratory surgery, even if radiological test results fail to indicate malignancy. The test was developed by Vermillion, Inc. (OTC: VRMLQ.PK), a molecular diagnostics company, in cooperation with Quest Diagnostics (NYSE: DGX), the world's leading provider of cancer diagnostics. Quest Diagnostics, which is a long-time investor in research and development of the OVA1 technology, has exclusive rights to offer the test to the clinical reference laboratory market in the U.S. for three years.

"When combined with other clinical information, the OVA1 biomarker panel can help assess the likelihood of malignancy of an ovarian tumor before surgery and facilitate decisions about referral to a gynecologic oncologist," said Frederick R. Ueland, M.D., principal investigator of the prospective, multi-center OVA1 clinical trial. Dr. Ueland is an associate professor gynecologic oncology at the University of Kentucky's Markey Cancer Center.

The OVA1 Test is an in vitro diagnostic multivariate index (IVDMIA) test that combines the results of five immunoassays using a proprietary unique algorithm to produce a single numerical score indicating a women's likelihood of malignancy. The OVA1 Test provides a new option in the pre-operative evaluation to help physicians assess if a pelvic mass is benign or malignant in order to help determine whether to refer a woman to a gynecologic oncologist for surgery. Numerous clinical practice guidelines recommend that women with ovarian cancer be under the care of a gynecologic oncologist. However, only an estimated one third of women who undergo surgery for possible ovarian cancer are referred to these specialist surgeons for their surgery.(1)

Vermillion received the Society for Gynecologic Oncologists (SGO) Basic Science Poster Award for an abstract on the performance of its OVA1 Test presented at SGO's 38th Annual Meeting on Women's Cancer in 2007. In reviewing the test application, the FDA evaluated results of a prospective, double-blind clinical trial which included 27 demographically mixed sites representative of institutions where ovarian tumor subjects may undergo a gynecological examination.

"Surgery in the hands of a gynecologic oncologist is usually associated with more favorable patient outcomes," said Jon R. Cohen, M.D., chief medical officer and senior vice president, Quest Diagnostics. "Physicians often do not know if a woman's pelvic mass is malignant or benign until she undergoes surgery. The OVA1 Test is the first FDA-cleared blood test to help clinicians determine whether to refer a woman to a gynecologic oncologist or have a gynecologic oncologist present at the time of surgery. We believe this test will help drive more favorable patient outcomes."

"Unfortunately, advances in ovarian cancer diagnosis and treatment are few and far between. It is fitting that September, Ovarian Cancer Awareness Month, marks FDA's clearance of OVA1, a test that represents an important step forward toward improved outcomes," said Gail S. Page, executive chairperson of the board of directors of Vermillion. "Quest Diagnostics had the foresight to recognize the potential value of this novel multivariate assay and supported its development. We look forward to collaborating to bring this new diagnostic option to the many women who will benefit from specialist care."

The FDA clearance of OVA1 makes Quest Diagnostics the only diagnostic testing company to offer FDA cleared tests for ovarian cancer in the pre- and post-surgical settings. In addition to offering the OVA1 Test, Quest Diagnostics was the first laboratory company to provide a new lab test that the FDA cleared in the third quarter of 2008 as an aid for monitoring for recurrence of epithelial ovarian cancer.

The OVA1 Test will be available for physician use in the fourth quarter of this year.

Ovarian cancer is the leading cause of death from gynecologic cancers in the United States and the fifth-leading cause of cancer deaths in women.(2) Approximately 21,600 new cases of ovarian cancer will be diagnosed in the U.S. in 2009, and approximately 14,600 women will die of the disease.(3)

About the OVA1 Test

The OVA1 Test is a qualitative serum test that combines the results of five immunoassays into a single numerical score. It 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. 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 a proprietary algorithm to determine the likelihood of malignancy in women with pelvic mass for whom surgery is planned.

The OVA1 Test 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.

About Vermillion

Vermillion, Inc. is dedicated to the discovery, 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, hematology, cardiology and women's health. Vermillion is based in Fremont, California. Additional information about Vermillion can be found on the Web at *www.vermillion.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 *www.QuestDiagnostics.com*.

(1) Journal of the National Cancer Institute, Vol. 98, No. 3, February 1, 2006

(2) Greenlee RT, Murray T, Bolden S, Wingo PA. Cancer statistics, 2000. CA Cancer J Clin. 2000;50(1):7-33

(3) 2009 American Cancer Society

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