OVA1 Blood Test Now Available to Aid Pre-surgical Evaluation of Women for Ovarian Cancer

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FDA-cleared test helps direct women to the most appropriate surgeon, promoting better outcomes

MADISON, N.J. and FREMONT, Calif., March 9, 2010 /PRNewswire via COMTEX/ -- OVA1(TM), the first blood 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, is now available nationally through Quest Diagnostics, Inc. (NYSE: DGX), the world's leading cancer diagnostics provider. With the availability of OVA1, physicians can assess, prior to a planned surgery, the likelihood that a woman's ovarian mass is malignant in order to direct her to the most appropriate surgeon, promoting more favorable treatment outcomes. Vermillion, Inc. (OTC: VRML.PK), a molecular diagnostics company, developed the test in cooperation with Quest Diagnostics.

OVA1 is the first FDA-cleared protein-based *in vitro* diagnostic multi-variate index assays (IVDMIA), a new class of state-of-the-art software-based diagnostics. The test combines the results of five well-established protein biomarkers to produce a single numerical result to help a physician classify the likelihood that a woman's mass is cancerous or benign.

"The availability of a new test that can help gynecologists and other physicians determine the likelihood a woman's mass is benign or malignant is a significant development in the battle against this devastating disease," said Karen Orloff Kaplan, MSW, MPH, Sc.D., chief executive officer of the Ovarian Cancer National Alliance, a leading patient advocacy group. "It is a big step towards helping each woman get the most appropriate care for her unique situation."

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.(1) Ovarian masses affect an estimated one million women and lead to as many 300,000 ovarian mass surgeries in the United States each year, according to an analysis by third parties on behalf of Quest Diagnostics.

Clinical practice guidelines recommend that women with ovarian cancer be under the care of a gynecologic oncologist. Yet, pre-surgical evaluations of ovarian masses, which include clinical evaluation and radiological tests such as CT scans and ultrasound, may provide inconclusive evidence of cancer. An estimated one third of initial surgeries for ovarian cancer are performed by gynecologic oncologists.(2)

"Studies show that surgery performed by a gynecologic oncologist to remove a cancerous ovarian mass is associated with more favorable outcomes," explained Fred Ueland, M.D., associate professor gynecologic oncology at the University of Kentucky's Markey Cancer Center and principal investigator of the prospective, multi-center OVA1 clinical trial evaluated by the FDA. "Based on my clinical experience, I believe OVA1 will not only help identify more women with ovarian cancer for referral to a gynecologic oncologist and improve cancer treatment outcomes, but it also will give other women greater confidence that their ovarian tumor is benign."

In a prospective clinical study, OVA1, when combined with pre-surgical clinical and radiological assessments and used by non-gynecologic oncologists, detected 92 percent of malignant ovarian masses compared to 72 percent without OVA1. In addition, 14 of 20 woman who participated in the study whose cancer was missed by pre-surgical clinical and radiological assessments would have been identified as having malignant ovarian masses had OVA1 results also been evaluated prior to their surgeries.

"Too often, a gynecologist will operate on a patient for an ovarian mass only to find an invasive malignancy requiring the skill of a specialist to remove," said Jon R. Cohen, M.D., senior vice president and chief medical officer, Quest Diagnostics, and a surgeon. "When this happens, the physician may need to prolong or terminate and reschedule the operation unless a gynecologic oncologist is readily available. OVA1 may help gynecologists and other physicians direct more women with cancer to a gynecologic oncologist for their first and hopefully only surgery."

Approximately 21,600 new cases of ovarian cancer will be diagnosed in the United States in 2009, and approximately 14,600 women will die of the disease.(3)

The FDA announced it had cleared OVA1 in September 2009, and Quest Diagnostics is the only national laboratory services provider to offer it broadly in the United States. For more information, physicians and patients should refer to www.QuestDiagnostics.com or www.QuestDiagnostics.com/womenscancers. Physicians may also refer to www.Vermillion.com.

About OVA1

OVA1 is the first protein-based *in vitro* diagnostic multi-variate index assays (IVDMIA), a new class of state of the art software-based diagnostics, cleared by the FDA. 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.

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.

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.

Certain matters discussed in this press release contain forward-looking statements that involve significant risks and uncertainties, including statements regarding Vermillion's plans, objectives, expectations and intentions. These forward-looking statements are based on Vermillion's current expectations. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, Vermillion notes that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. There are no guarantees that Vermillion will succeed in its efforts to commercialize ovarian cancer or OVA1(TM) diagnostics products in 2010 or during any other period of time. Factors that could cause actual results to materially differ include but are not limited to: (1) uncertainty in obtaining intellectual property protection for inventions made by Vermillion; (2) unproven ability of Vermillion to develop, and commercialize diagnostic products based on findings from its disease association studies; (3) uncertainty as to whether Vermillion will be able to obtain any required regulatory approval of its future diagnostic products; (4) uncertainty of market acceptance of its OVA1(TM) diagnostic test or future diagnostic products, including the risk that its products will not be competitive with products offered by other companies, or that users will not be entitled to receive adequate reimbursement for its products from third party payers such as private insurance companies and government insurance plans; (5) uncertainty that Vermillion will successfully license or otherwise successfully partner with third parties to commercialize its products; (6) uncertainty whether the trading in Vermillion's stock will become significantly less liquid or Vermillion's ability to relist its shares on the NASDAQ Global Market or on other national securities exchange; and (7) other factors that might be described from time to time in Vermillion's filings with the Securities and Exchange Commission. All information in this press release is as of the date of this report, and Vermillion expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in Vermillion's expectations or any change in events, conditions or circumstances on which any such statement is based, unless required by law.

(1) Jemel A, Siegel R, Ward E, Hao Y, Xu J, Thun M. Cancer Statistics 2009. CA: A Cancer Journal for Clinicians. 2009;59:225-249.

(2) Journal of the National Cancer Institute, 2006;98:172-80.

(3) American Cancer Society 2009.

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