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PIVOTAL DATA PUBLISHED FOR FIRST BIOMARKER COMBINATION TEST TO DETERMINE RISK OF OVARIAN CANCER IN WOMEN WHO PRESENT WITH PELVIC MASS

Article in Gynecologic Oncology Supports Use of Fujirebio Diagnostics' HE4 Test with CA125 for Risk Stratification of Women with Suspected Ovarian Cancer

MALVERN, Pa. January 26, 2009 – A pivotal clinical trial published in the January 2009 issue of the journal *Gynecologic Oncology* demonstrated the utility of combining Fujirebio Diagnostics' HE4 and the CA125 test as an aid in estimating the risk of epithelial ovarian cancer in premenopausal or postmenopausal women presenting with pelvic mass. The HE4 test, which is under review by the U.S. Food and Drug Administration (FDA), was reported to successfully stratify patients into high- and low-risk groups when combined with CA125.

The combination test uses the results from two simple blood tests – CA125 and HE4 – and the Risk of Ovarian Malignancy Algorithm (ROMA™) to identify patients at a high risk of having ovarian cancer. CA125 is the current gold standard for monitoring patients diagnosed with ovarian cancer. The HE4 assay was recently cleared by the FDA as an aid for monitoring recurrence of epithelial ovarian cancer (EOC), the most common type of ovarian cancer. Combining the HE4 and CA125 tests may enable physicians to pre-operatively identify those patients with a high risk of malignancy.

“Research suggests that ovarian cancer patients have better outcomes and improved survival when treated by gynecologic oncologists, surgeons that are trained and specialize in the treatment of patients with EOC,” said Richard G. Moore, MD, Director of Medical Education, Program in Women's Oncology at Women and Infants' Hospital, and Assistant Professor, Obstetrics and Gynecology, Brown University, Providence, R.I, and lead author of the *Gynecologic Oncology* paper. “Combining measurements of HE4 and CA125 helps us to identify women who are at high risk of ovarian cancer when they present with an ovarian cyst or mass. This will increase these women's chances of receiving optimal treatment.”

The HE4 test and ROMA algorithm are the product of research efforts aimed at identifying combinations of biomarkers to add sensitivity to the existing CA125 test, which is limited in its sensitivity and specificity as well as its ability to detect early stage EOC. The pivotal data provide important validation for the use of the HE4 test in combination with CA125 in estimating EOC risk in women presenting with pelvic mass and, when used in conjunction with other clinical methods, may help to ensure these women receive appropriate treatment.

Dr. Moore and his colleagues conducted a prospective, double-blind, multicenter trial involving 566 women with pelvic mass who were scheduled for surgical intervention. Blood samples were obtained from study participants to measure for levels of HE4 and CA125. Two separate algorithms for premenopausal and postmenopausal women stratified patients into low- and high-risk groups. All patients then underwent surgical removal of the pelvic mass. All tissue specimens were examined to verify the diagnoses made by study site pathologists.

The combination of HE4 and CA125 with the ROMA algorithm was found to be highly accurate in assigning patients to high- and low-risk groups, with 88.7% of EOCs and low malignant potential tumors correctly classified as high-risk. For the postmenopausal group the combination test had a sensitivity of 92.3%, a specificity of 74.7%, and a negative predictive value (NPV) of 92.6%. For the premenopausal group the combination test had a sensitivity of 76.5%, a specificity of 74.8%, and an NPV of 95.0%.

“Research demonstrates that patients who are treated by a gynecologic oncologist fare better than patients who are treated by a non-specialist. Any additional diagnostic tools that help the physician identify who is at a high risk of EOC may result in more optimal referral patterns and improved outcomes,” said Karen Orloff Kaplan, Sc.D., Chief Executive Officer of the Ovarian Cancer National Alliance.

About HE4

HE4 in a manual format is currently FDA cleared for monitoring recurrent or progressive disease in patients with EOC, and CE-marked in Europe as an aid in estimating the risk of EOC in premenopausal or postmenopausal women presenting with a pelvic mass. The test is currently available in the U.S. exclusively through Quest Diagnostics Incorporated (NYSE: DGX). The HE4 manual test and corresponding Risk of Ovarian Malignancy Algorithm (ROMA™) are pending clearance by the FDA for use in women who present with a pelvic mass.

About Ovarian Cancer

Ovarian cancer is the leading cause of death from gynecologic cancers in the U.S. and the fifth-leading cause of cancer death in women. It accounts for 31% of cancers of the female genital organs. There are an estimated 22,000 new cases annually in the U.S. Women who are postmenopausal are at the greatest risk for ovarian cancer. In their lifetimes, 1 in 72 women will develop ovarian cancer.

Ovarian cancer is difficult to diagnose because its symptoms are easily confused with other non-cancerous conditions: bloating, pelvic or abdominal pain, difficulty eating or feeling full quickly, urgent or frequent urination, gastrointestinal upset and unexplained fatigue. Three quarters of cases of ovarian cancer are diagnosed at an advanced stage, when it is fundamentally incurable. Of patients who are diagnosed early (Stage I-II), more than 90 percent will live past five years. However, only 20 percent of cases are diagnosed in the early stages.

About Fujirebio Diagnostics

Fujirebio Diagnostics is the premier cancer diagnostics company and the industry leader in cancer biomarker assays. Fujirebio Diagnostics specializes in the clinical development, manufacturing and commercialization of in-vitro diagnostic products for the management of human disease states, with an emphasis in oncology. Fujirebio Diagnostics is one of the group companies of Miraca Holdings Inc. in Japan, set up in July 2005 to combine Fujirebio Inc., the leading in-vitro diagnostics company, and SRL, Inc., the top provider of clinical laboratory testing services in Japan. Fujirebio Diagnostics has a worldwide distribution network, which enables physicians and patients to access its diagnostic products. For more information about Fujirebio Diagnostics, please call 610-240-3800 or visit www.fdi.com.

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