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Contact: Stephanie Euler
Stern + Associates
(908) 276-4344 ext. 213
stephanie@sternassociates.com

Researchers Identify Indicator of Ovarian Cancer
Combination of Tests Could Lead to Earlier Detection of the Silent Killer

MALVERN, Pa., December 17, 2007 – Women with elevated levels of a substance called HE4 in their blood may be more likely to have ovarian cancer, according to results of a prospective study recently published on-line in the journal of *Gynecologic Oncology*. The findings offer a positive step forward in the quest for a test for early detection of the disease dubbed the “silent killer” for which there is no adequate screening test.

“Ovarian cancer is often difficult to diagnose because symptoms are often recognized in the late stages of the disease when ovarian cancer is fundamentally incurable,” said Lead Researcher Dr. Richard Moore, assistant professor in the Program for Women’s Oncology at Women and Infants’ Hospital / Brown University. “Our research was directed at identifying those unique characteristics or ‘biomarkers’ of the disease that might one day help us detect this disease earlier.”

Currently, the gold standard for monitoring ovarian cancer is a test that measures for elevated levels of the CA-125 substance in the blood. The test can be limited in detecting all types of ovarian cancer, prompting researchers to seek out additional biomarkers that offer higher sensitivity and can be indicative of the disease to complement CA-125.

In this study, Moore’s team evaluated nine potential biomarkers in 259 patients with pelvic mass. Researchers measured levels of each biomarker within the women’s blood and then compared the results with biopsies of their tumors. With 72.9 percent sensitivity and 95 percent specificity, HE4 was the most effective biomarker for detecting ovarian cancer. When CA-125 was added, the result was an even more powerful combination of tests with sensitivity for detecting the disease increased to 76.4 percent.

“Our results show testing women suspected of ovarian cancer for both CA-125 and HE4 could possibly lead to a screening and diagnostic tool,” adds Moore. “This is exciting news, particularly for women in the earliest stages of the disease when it is most treatable.”

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Moore's study noted HE4 as the best single marker for Stage I disease. Seventy to 75 percent of ovarian cancers are diagnosed at a late stage when the five-year overall survival rate may only reach up to 50%. However, in women diagnosed with Stage I disease, the probability of a cure approaches 90-95 percent.

"This is an encouraging development not only for ovarian cancer patients, but for all women with ovarian cysts as it can be challenging to distinguish malignant tumors from benign ones with current methods," said Dr. Olle Nilsson, vice president and chief scientific officer of Fujirebio Diagnostics, the developers of the CA-125 test. "A combination of tests could help clinicians better define ovarian cysts so they can determine the most appropriate treatment regimen for their patients."

Fujirebio Diagnostics has developed a manual test for HE4 and will be developing automated formats of the test for Fujirebio instruments, as well as, the Abbott Architect. The company plans to submit to the U.S. Food and Drug Administration (FDA) for regulatory clearance of the HE4 test later this year.

About Fujirebio Diagnostics, Inc.

Fujirebio Diagnostics, Inc. is a premier diagnostics company and the industry leader in 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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