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

New Ovarian Cancer Test Now Available in Europe
Fujirebio Diagnostics' HE4 Granted CE Marking

MALVERN, Pa., March 4, 2008 – European women facing “the silent killer” now have access to a breakthrough test to identify their risk of ovarian cancer. Fujirebio Diagnostics, the industry leader in biomarker assays, announces that its HE4 test is now CE marked, a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). Now available for sale throughout the European Union, the simple blood test measures for a substance known as HE4, which many studies have shown can be elevated in epithelial ovarian cancers. The test is intended to be used in conjunction with the CanAg CA 125 EIA or the Abbott ARCHITECT CA 125 II as an aid in estimating risk of epithelial ovarian cancer in women presenting with a pelvic mass prior to surgery.

For many years CA 125 has been the gold standard for monitoring ovarian cancer; however, this test is limited in its sensitivity and specificity as well as its ability to detect all types of ovarian cancer, prompting researchers to seek out additional indicators or “biomarkers” to complement CA 125 that offer higher sensitivity and can be indicative of the disease.

“The new HE4 test is a major step in the fight against ovarian cancer worldwide,” said Dr. Olle Nilsson, vice president and chief scientific officer of Fujirebio Diagnostics. “The same data used to support the CE mark certification has been submitted to the U.S. Food and Drug Administration (FDA) and we hope to see availability of the test in the United States during 2008.”

With the HE4 test, risk for epithelial ovarian cancer is determined by using a mathematical algorithm that combines the HE4 and CA 125 values. The test is also intended to be used as an aid in monitoring response to therapy for patients with invasive epithelial ovarian cancer.

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Recently, the results of a study which looked at the ability of various combinations of seven different biomarkers all known to be expressed in ovarian cancer were published. The paper, which was published in February 2008 in the journal *Gynecologic Oncology*, showed that as a single biomarker, HE4 had the highest sensitivity for detecting ovarian cancer, especially Stage I disease, and that when CA 125 and HE4 are combined they are a more accurate predictor of cancer than either alone. These findings, combined with the new CE mark, offer a positive step in the race for earlier detection and treatment.

“This powerful combination increases the sensitivity for detecting a disease that is often difficult to diagnose because symptoms can be confusing for patients to recognize,” said Lead Researcher Dr. Richard Moore, assistant professor of the Program for Women’s Oncology at Women and Infants’ Hospital in Providence, Rhode Island, USA. “Our research offers hope for a more effective way to manage and treat ovarian cancer as well as a possible screening tool for women in the earliest stages of the disease when it is most treatable.”

This is the first commercially available test which when used in combination with another test and a mathematical algorithm can estimate the risk of finding ovarian cancer upon surgery in women who present to their physician with a pelvic mass.

Fujirebio Diagnostics has developed a manual test for HE4 and will be developing automated formats of the test for Fujirebio instruments. The HE4 test is awaiting clearance by the FDA and is not available for sale in the United States.

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.