



Women & Infants'

FOR IMMEDIATE RELEASE

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

MALIGNANT TUMOR OR BENIGN CYST?:

Researcher from Women & Infants'/Alpert Medical School Says Combination Tests Could Identify Women's Ovarian Cancer Risk for More Accurate Diagnosis, Treatment

TAMPA, Fla., March 10, 2008 – The results of a study presented today at the Society of Gynecologic Oncology's 39th Annual Meeting on Women's Cancer offer a promising development on the path toward better management of ovarian cancer. Researchers say testing women suspected of having ovarian cancer for a combination of proteins, or biomarkers in the blood called HE4 and CA 125, could be the key to predicting a woman's risk for the disease dubbed the "silent killer." Currently there is no adequate diagnostic test for ovarian cancer.

"Roughly 20 percent of women will be diagnosed with an ovarian cyst or tumor at some point in their life, and only a small percentage of these women will be diagnosed with ovarian cancer," said Lead Researcher Richard Moore, M.D., assistant professor at The Warren Alpert Medical School of Brown University and a gynecologic oncologist in the Program in Women's Oncology at Women & Infants' Hospital of Rhode Island. "The problem is that current methods for distinguishing benign ovarian tumors from malignant ones are limited and as a result, women must undergo surgery without an accurate assessment as to their risk for having ovarian cancer prior to their surgery."

Dr. Moore notes that fewer than half of all ovarian cancer patients have their initial surgery performed by a gynecologic oncologist or surgeon with specialized training in the management of ovarian cancer. "Our research is aimed at identifying patients at high risk for harboring an ovarian cancer so that they receive the right care from the right physician."

Currently, CA 125 is the only blood test that can be used to help predict a woman's risk for ovarian cancer and to help with the clinical management of the disease. However, CA 125 alone lacks the sensitivity required for the detection of ovarian cancer prompting researchers to look at the ability of combinations of biomarkers to predict the presence of ovarian cancer. Earlier this year, Dr. Moore published results of a pilot study in the journal of *Gynecologic Oncology* evaluating nine potential biomarkers and the ability of multiple marker combinations to predict the risk for ovarian cancer in women. His findings showed the combination of HE4 and CA 125 provided the highest level sensitivity and specificity out of all marker combinations for predicting the presence of ovarian cancer.

In a prospective, double-blinded, multicenter clinical trial, Dr. Moore and his team studied 496 women presenting with pelvic mass or ovarian cysts to determine if tests targeting multiple markers utilizing HE4 and CA 125 and a predictive algorithm could accurately assess the risk for epithelial ovarian cancer prior to surgery. Researchers measured levels of the biomarkers within the women's blood and then compared the results with biopsies of their tumors. The combination of biomarkers performed well in both pre- and post-menopausal women, accurately stratifying 95 percent of patients with epithelial cancer as high risk and 75 percent of benign cases as low risk.

"Studies suggest women with ovarian cancer have better outcomes and increased survival when treated by surgeons trained in the management of ovarian cancer and at institutions specializing in the care of women with this disease," adds Dr. Moore. "By using the combination of HE4 and CA 125 as a model to assess a women's risk for ovarian cancer, physicians can better triage patients for care and refer them to the appropriate specialist – whether at a community hospital or large academic institution."

"Together, HE4 and CA 125 offer a powerful combination that could dramatically change the way ovarian cancer is managed at all stages of care," said Dr. Olle Nilsson, vice president and chief scientific officer of Fujirebio Diagnostics, the developers of the CA 125 test. "As research continues to progress, it is our hope that a test for HE4 and CA 125 could eventually lead to a plausible screening tool."

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 CE marked in Europe. The company has applied to the U.S. Food and Drug Administration (FDA) and hopes to see availability of the test in late 2008.

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.

About Women & Infants Hospital

Women & Infants Hospital of Rhode Island, a Care New England hospital, is one of the nation's leading specialty hospitals for women and newborns. The primary teaching affiliate of The Warren Alpert Medical School of Brown University for obstetrics, gynecology and newborn pediatrics, Women & Infants is the ninth largest obstetrical service in the country with more than 9,000 deliveries per year. In 2003, Brown University and Women & Infants were named a National Center of Excellence in Women's Health by the U.S. Department of Health and Human Services. Women & Infants has been named one of the best hospitals in gynecology in the 2000, 2001 and 2004 editions of *America's Best Hospitals in U.S. News & World Report*. For information about Women & Infants, log on to www.womenandinfants.org.

###