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FUJIREBIO DIAGNOSTICS (FDI) TO DEVELOP NEW MARKERS FOR USE WITH CA125II FOR EARLY DETECTION OF OVARIAN CANCER

In research licensing agreement with Pacific Northwest Research Institute, Fujirebio Diagnostics to combine new tumor markers with CA125II for greater diagnostic accuracy

Malvern Pennsylvania, July 25, 2002---- Fujirebio Diagnostics, Inc. (FDI), a leading oncology diagnostics company, announced today that it has acquired the rights from Pacific Northwest Research Institute (PNRI) to develop two newly discovered ovarian tumor markers, mesothelin and HE4.

Pre-clinical research has shown that mesothelin and HE4 augment the diagnostic potential of FDI’s serum-based assay, CA125II, which is currently the standard of care for management of ovarian cancer. Based on research findings, combining the three ovarian cancer tumor markers may result in dramatically improved diagnostic performance, particularly for the detection of early stage disease.

“The development of a complementary assay for use with CA125II for improved use in early detection of ovarian cancer represents another step forward in the standard of care,” said Aris Petropoulos, President and Chief Operating Officer of FDI. “Successfully developing these tumor markers will create a useful tool for physicians to use in the early detection of ovarian cancer and will have a tremendous impact in saving women’s lives.”

Serum-based assays are useful in the clinical setting due to their cost-effectiveness and ease-of-use. Ovarian cancer researchers continue to work on improving the sensitivity and specificity of serum-based markers, with the goal of achieving the highest level of diagnostic accuracy possible. Recent studies suggest that combining several select tumor markers, possibly in a multiplex mode, could lead to a more sensitive and specific assay for the early detection of ovarian cancer. While each marker has significant serum-detection abilities, the combination of
these three markers represents a unique synergy that has the potential to increase the likelihood that ovarian cancer is diagnosed at an early, more treatable stage.

“Multiplex assays are a novel development in the area of cancer detection,” said Daniel O’Shannessy Ph.D., Chief Scientific Officer of FDI. “They are currently used in a limited capacity, but have the potential to profoundly change diagnostics. Combining mesothelin and HE4 with CA125II has a potentiating effect on the diagnostic ability of CA125II. Our ultimate goal is to push the envelope of detection to as-close-to-onset as possible.”

In its early stages, ovarian cancer has no symptoms. Therefore, over 75% of new cases remain undiagnosed until they reach stage 3 or 4. At that point, the 5-year survival rate is only 17%, compared with a cure rate of 80%-90% for ovarian cancers diagnosed at stage 1. According to data from the American Cancer Society, each year there are an estimated 23,400 new cases of ovarian cancer and 13,900 ovarian cancer-related deaths. Ovarian cancer is fifth in incidence of cancers among women, but the low cure-rate makes this an especially deadly disease.

“We are happy that work from the Tumor Immunology Laboratory at PNRI has been licensed to Fujirebio Diagnostics for further clinical development,” said Ingegerd Hellstrom, Ph.D. Dr. Hellstrom developed the HE4 and mesothelin assays and is the lead scientist on the project.

According to Dr. Hellstrom, “The development of the mesothelin and HE4 assays was a collaborative effort.” Dr. Hellstrom collaborated with her former colleagues and a number of contributors to complete the research necessary for development of both assays. “PNRI became involved with HE4 after overexpression of the HE4 gene was demonstrated in ovarian cancer.”

Pacific Northwest Research Institute, a private non-profit biomedical and clinical research laboratory in Seattle, focuses on the pathogenesis and prevention of disease, especially diabetes and cancer. Currently, scientists at PNRI are conducting research in tumor immunology, autoimmune disease, growth factor and metabolic signal transduction pathways, oxidative stress and population screening for diabetes and cancer. They are also developing a pancreatic islet transplantation program to treat patients with diabetes. Early detection of various cancers is a major focus of the Hellstrom laboratory.

Fujirebio Diagnostics, Inc. (FDI), is a premier diagnostics company and the industry leader in Tumor Marker assays specializing in the clinical development, manufacturing and commercialization of in vitro diagnostic products for the detection, prognosis, and monitoring of human disease states with an emphasis in Oncology. The company, formerly known as Centocor Diagnostics, was acquired by Fujirebio, Inc. of Tokyo, Japan in November 1998. FDI utilizes its world-wide distribution network to enable access by physicians and patients to its diagnostic products.

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