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**FUJIREBIO DIAGNOSTICS AND ROCHE DIAGNOSTICS SIGN AGREEMENT  
FOR NEW OVARIAN CANCER TEST**

*Fujirebio Diagnostics' HE4 Test will be Available Through Roche Diagnostics'  
Automated Immunoassay Analyzers*

**MALVERN, PA and BASEL, SWITZERLAND – Dec. 16, 2008** – Fujirebio Diagnostics, Inc. and Roche Diagnostics announced today a worldwide license and supply agreement for the HE4 ovarian cancer test. Under the agreement, Roche will develop an assay kit utilizing Fujirebio Diagnostics' HE4 test on its automated immunoassay analyzers.

The HE4 test was developed by Fujirebio Diagnostics to be used in conjunction with the company's existing CA125 biomarker, the current gold standard for monitoring ovarian cancer. This combination of biomarkers, as published clinical data shows, provides clinicians with a diagnostic tool that can provide higher sensitivity and specificity than CA125 alone. Improved sensitivity and specificity should allow clinicians to distinguish between benign and malignant pelvic masses more accurately, helping to ensure that patients receive appropriate therapy earlier.

“This novel biomarker HE4 will allow our longstanding partner Roche Diagnostics to provide clinicians worldwide with a much needed tool to better define a pelvic mass, enabling women at higher risk for cancer to see the right physician earlier,” said Paul Touhey, President and Chief Executive Officer, Fujirebio Diagnostics.

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

HE4 in a manual format is currently FDA-cleared for monitoring recurrent or progressive disease in patients with epithelial ovarian cancer (EOC), and CE-marked in Europe as an aid in estimating the risk of EOC in premenopausal or postmenopausal women presenting with pelvic mass. The HE4 manual test and corresponding Risk of Ovarian Malignancy Algorithm (ROMA™) are pending clearance by the United States Food and Drug Administration (FDA) for use in women who present with a pelvic mass.

“The HE4 test is another important pillar of our broad tumor marker test menu. We expect that the HE4 test will contribute significantly to our future growth in the area of oncology” said Dirk Ehlers, Head of Roche Professional Diagnostics.

### **About Ovarian Cancer**

Ovarian cancer is the leading cause of death from gynecologic cancers in the United States 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 United States. Women who are postmenopausal are at the greatest risk for ovarian cancer. In their lifetimes, 1 in 72 women will develop ovarian cancer.

### **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](http://www.fdi.com).

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

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