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Fujirebio Diagnostics Receives FDA Approval for the MESOMARK[®] Assay for the Management of Mesothelioma Patients

MALVERN, Pa., January 25, 2007 – Fujirebio Diagnostics, Inc. (FDI) received approval from the Food & Drug Administration (FDA) under the Humanitarian Device Exemption (HDE) program for the MESOMARK[®] Assay, the world's first *in-vitro* test for mesothelioma, a form of cancer linked to asbestos exposure. Via a simple blood test, the MESOMARK test enables doctors to monitor patients diagnosed with biphasic or epithelioid mesothelioma.

“The MESOMARK test signifies the beginning of a new era in monitoring mesothelioma malignancies,” said Dr. W. Jeffrey Allard, vice president and chief scientific officer of Fujirebio Diagnostics. “As the first *in-vitro* test for patients with this aggressive disease, it will enable doctors to more accurately detect recurrence and monitor treatment of patients.”

The MESOMARK Assay test kit was developed to measure levels of a biomarker, mesothelin, in serum. Biomarkers are substances found in higher-than-normal concentrations in the blood, urine or body tissues of patients with certain types of cancers. The test may be used to monitor patients confirmed as having mesothelioma, for recurrence in patients following surgery, or for measuring response to therapies. The test will be available nationally to physicians, via a central reference lab, in the first quarter of 2007.

“Current diagnostic tests are less than ideal for quantification of changes in tumor volume, which is key to managing the disease,” continued Allard. “As the MESOMARK results correlate with tumor volume*, it provides a much needed tool for monitoring patient status. It is our plan to collect additional data in the future to support the use of the test to detect mesothelioma.”

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*Robinson BWS, Creaney J, Lake R, et al. *Lancet*. 2003;362: 1612-1616

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“Development of a reliable biomarker is a major advance in the care of mesothelioma,” said Chris Hahn, executive director of the Mesothelioma Applied Research Foundation (Meso Foundation). “Fujirebio Diagnostics and the MESOMARK test are now making it possible – with a simple blood test –to monitor response to treatment and to detect recurrence following treatment. This provides an important head start to patients racing against this aggressive cancer.” The Meso Foundation is the national research funding, patient support and advocacy organization dedicated to eradicating mesothelioma as a life-threatening disease.

Mesothelioma affects the sac lining the chest, the abdominal cavity or the area around the heart. Many people with this cancer have been employed in environments where they inhaled asbestos, such as in the shipbuilding and construction industries. Most insulation and construction materials manufactured before the mid-1970s contained asbestos, including insulation on pipes and boilers; fireproofing spray; roof, floor, and ceiling tiles; and brakes and clutches. Others have been exposed to asbestos in households or the general environment. Currently, more than 100 million people worldwide have been exposed to asbestos through their professions over the years – often unknowingly – including shipyard workers, insulators, boilermakers, plumbers and maintenance workers.

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 a wholly owned subsidiary of Fujirebio Inc. Fujirebio Inc. is a leading healthcare company in Japan with a focus on diagnostics, and is a group company of Miraca Holdings. 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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