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NYU Study Validates Use of the Fujirebio Diagnostics MESOMARK[®] Test for Monitoring an Asbestos-linked Cancer

MALVERN, Pa., February 7, 2007 – There is new hope for the thousands of Americans suffering from mesothelioma, an aggressive form of cancer linked to asbestos exposure. Results from a recent study conducted by researchers at New York University (NYU) School of Medicine¹ show the MESOMARK[®] Assay, the world's first and only *in vitro* test for monitoring mesothelioma developed by Fujirebio Diagnostics, Inc., is an effective way to measure proteins within the blood that reflect changes in disease. The findings represent a major milestone in the management of mesothelioma, as the test may enable doctors to more accurately monitor patients for treatment.

Mesothelioma causes fluid to accumulate in the sac lining of the chest, the abdominal cavity or the area around the chest. Primarily caused by work-related asbestos exposure, physicians have long suspected it could be identified by the presence of soluble mesothelin-related proteins (SMRP) that are released into the blood stream by diseased cells. Previously, these proteins have been difficult to detect, and patient monitoring required a comprehensive series of diagnostic tests. Even the most advanced tests available are of limited utility in evaluating changes in tumor volume, a key factor for monitoring patient status and response to therapies.

In the study led by Dr. Harvey Pass, Department of Cardiothoracic Surgery, NYU School of Medicine, researchers used the MESOMARK Assay to test serum and pleural effusions of diagnosed malignant mesothelioma patients. Results from the study, presented recently at the Society of Thoracic Surgeons Annual Meeting in San Diego, revealed that these patients had statistically significantly higher amounts of SMRP than those in the control group which included individuals with well documented asbestos exposure, as well as patients with other cancers. Additionally, SMRP levels were found to rise among diagnosed patients as the disease progressed to more advanced stages.

“As a relatively rare and often misdiagnosed disease, mesothelioma has been somewhat of a

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¹ H.I. Pass, F. Steiner, A. Ivanova, S. Ivonov, J. Allard. Validation of Soluble Mesothelin Related Peptide (SMRP) Level Elevation in Mesothelioma Serum and Pleural Effusions; Presented at the Society of Thoracic Surgeons Annual Meeting, January 30th, 2007.

+ NYU School of Medicine, New York, New York; Fujirebio Diagnostics, Malvern, Pa.

mystery to the medical world,” said Dr. Harvey Pass. “For years, we’ve believed SMRP played a role in the classification of the disease, but there was no accurate way to confirm it. Our findings not only show that SMRP is indeed a valid biomarker for mesothelioma, but also justify further research as a prospective screening test. As we continue to learn more about this complex disease through tests such as Fujirebio Diagnostics’ MESOMARK Assay, we might finally be on our way towards improving survival rates and the quality of life for patients diagnosed with this aggressive and often fatal disease.”

“Mesothelioma can take as long as 75 years to develop after exposure to asbestos, yet once it does, it rapidly grabs hold of a person’s body. In fact, there is only about a 10 percent survival rate for patients after three years following diagnosis,” said Dr. W. Jeffrey Allard, vice president and chief scientific officer of Fujirebio Diagnostics. “The MESOMARK test may give physicians a way to determine how rapidly the disease is progressing and if they’re administering the appropriate treatment regimen. In the future, our hope is that it could one day lead to detection of mesothelioma at an early and potentially curable stage.”

Mesothelioma is often difficult to diagnose, as many of its symptoms are similar to numerous other conditions, including various forms of cancer. 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. It is estimated that 10,000 new cases are diagnosed each year worldwide.

Approved by the U.S. Food & Drug Administration (FDA) under the Humanitarian Device Exemption (HDE) program on January 24, 2007, the MESOMARK Assay test kit was developed by Fujirebio Diagnostics to measure levels of SMRP in serum of patients diagnosed with biphasic or epithelioid mesothelioma. Via a simple blood test, it may be used to monitor patients confirmed as having the disease, for recurrence in patients following surgery, or for measuring response to therapies.

The MESOMARK test will be available nationally to physicians, via a central reference lab, in the first quarter of 2007.

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.