Fujirebio Diagnostics, Inc. Receives FDA 510 (k) Clearance for First Biomarker to Monitor Lung Cancer

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MALVERN, Pa., May 31, 2011 /PRNewswire/ -- Fujirebio Diagnostics, Inc., today announced that the U.S. Food and Drug Administration (FDA) has granted 510 (k) clearance to the CYFRA 21-1™ EIA assay to monitor disease progression during the course of disease and treatment of lung cancer patients. This is the first biomarker assay kit to be cleared by FDA for use in the management of patients with lung cancer.

"The clearance of the CYFRA 21-1 assay kit adds to Fujirebio's growing portfolio of tumor marker assays for ovarian cancer, pancreatic cancer, breast cancer, and other malignancies," commented Monte Wiltse, Vice President of Sales and Marketing at Fujirebio Diagnostics. "Achieving FDA clearance of the CYFRA 21-1 assay kit for lung cancer is the first step in what we anticipate will be a strong pipeline of innovations that help physicians in the management of lung cancer."

The CYFRA 21-1 assay kit is indicated for the quantitative determination of soluble cytokeratin 19 fragments in human serum. It is to be used as an aid in monitoring disease progression during the course of disease and treatment in patients with lung cancer. Serial testing for patient CYFRA 21-1 assay values should be used in conjunction with other clinical methods used for monitoring lung cancer. Data submitted to FDA showed that changes in CYFRA 21-1 values correlated with changes in disease status in 76% of the studied patient population.

According to the Surveillance Epidemiology and End Results (SEER) database of the National Cancer Institute (NCI), an estimated 222,520 new cases of lung cancer were diagnosed in the U.S. in 2010, and roughly 157,300 Americans died of the disease.(1)

"FDA clearance of CYFRA 21-1 allows laboratories in the US the opportunity to provide a valuable diagnostic tool to oncologists in the management of lung cancer," said David Grenache, PhD, a Medical Director at ARUP Laboratories in Salt Lake City, UT. "ARUP Laboratories
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SOURCE [1]

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