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Abbott's ALK Test is Now Available in Europe

Abbott's ALK test is now available in Europe as a companion diagnostic test to aid in identifying patients for targeted lung cancer therapy.

Abbot has announced that it will expand the current CE-IVD product labeling for its Vysis® ALK Break Apart FISH Probe Kit, allowing the test to be marketed in the European Union as a companion diagnostic. The test is designed to detect rearrangements of the anaplastic lymphoma kinase (ALK) gene in advanced non-small cell lung cancer (NSCLC) patients who may be eligible for treatment with XALKORI (crizotinib), an oral first-in-class ALK inhibitor.

The Vysis ALK test kit uses Abbott's proprietary fluorescence in situ hybridization (FISH) technology and was the only diagnostic test used in multi-centre global clinical trials in conjunction with Pfizer's XALKORI (crizotinib). Patients in these global clinical trials for XALKORI were screened with Abbott's ALK FISH test to detect possible gene rearrangements and allow physicians to make important treatment decisions.

The Abbott test has been used by oncologists in the United States since it was co-approved with XALKORI by the U.S. Food and Drug Administration in August 2011. The test offers clinicians a standardised, clinically validated method to identify patients more likely to benefit from the new therapy. In Europe, the CE-IVD test has been available to laboratories since September 2011 and has been used primarily in academic studies and to support evaluations of new therapies.

"Laboratories throughout Europe are familiar with and experienced in using the Vysis ALK FISH test so they will be able to start testing lung cancer patients immediately to help doctors decide if XALKORI is the right treatment option for them," said Kristina Rodnikova, head of Abbott's molecular diagnostics business in Europe.

Similar to the Abbott ALK test's ability to identify patients for XALKORI therapy, Abbott's CE Marked PathVysion test, detects amplification of the HER-2 gene and acts as an aid in identifying patients for Herceptin (trastuzumab) therapy for breast and stomach cancer. In nearly 15 years of clinical experience, the FISH HER-2 assay has tested thousands of patients and allowed them to begin life-saving therapy with Herceptin. PathVysion was also the first FDA approved FISH-based companion diagnostic test.

A year of clinical laboratory experience since its approval in the United States has established the value of the Vysis ALK Break Apart FISH assay as a rapid, sensitive and specific test for detecting ALK gene rearrangements in patients with NSCLC. To date, no other tests for detecting patients with ALK-positive lung cancer have been validated in clinical trials performed to establish clinical benefit from XALKORI in the treatment of ALK-positive NSCLC.

Worldwide, lung malignancies are the leading cause of cancer deaths, with more than 1.6 million new cases diagnosed each year. About 85 percent of lung cancer patients have the non-small cell type and are usually diagnosed with advanced disease with a very low survival rate. Approximately 3 to 5 percent of those patients have rearrangements of the ALK gene and will respond to therapies like XALKORI, which block the ALK pathway.

More information on the Vysis ALK test and laboratories offering this test is available by contacting Abbott at 855-TEST-ALK or online at www.AbbottALK.com.

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