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Amoy Diagnostics gets nod for gene detection kit in China

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Singapore: Amoy Diagnostics' EML4-ALK Fusion Gene Detection Kit has received market approval from China's State Food and Drug Administration (SFDA). The SFDA regulates drugs and in vitro diagnostics in mainland China. The approval allows AmoyDx to market the EML4-ALK Fusion Detection test for clinical use in China.

The assay detects 21 different fusion products from rearrangements of the EML4 and ALK genes. RNA that has been purified from the FFPE tissue is first reverse transcribed to cDNA with RT enzyme supplied with the kit. The EML4-ALK fusion cDNAs are then specifically amplified with cross-junction PCR primers and qualitatively detected with fluorescent probes. The method has excellent sensitivity and accuracy, and has been validated on PCR instruments from several manufacturers. The test kits are assembled in AmoyDx's ISO13485-certified, GMP-compliant manufacturing plant.

The EML4-ALK fusion oncogene represents one of the newest molecular targets in non-small-cell lung cancer (NSCLC). First described in 2007, the fusion results from a small inversion within chromosome 2p. This inversion leads to expression of a chimeric tyrosine kinase having the N-terminal portions of echinoderm microtubule-associated protein-like 4 (EML4) fused to the intracellular kinase domain of anaplastic lymphoma kinase (ALK). The EML4-ALK protein possesses potent oncogenic activity both in vitro and in vivo. This activity can be blocked by small-molecule inhibitors such as Pfizer's Xalkori.

Amoy Diagnostics announced CE marking for the EML4-ALK Fusion Detection kit earlier, in January of 2013.

Amoy Diagnostics is the major provider of EGFR mutation detection kits in China. The kits are used to identify non-small cell lung cancer patients who will benefit from treatment with anti-EGFR drugs such as Iressa or Tarceva. The company works closely with AstraZeneca in China to promote molecular testing of lung cancer samples so that patients receive the most appropriate treatment option.

In addition to the EML4-ALK test, the AmoyDx EGFR, KRAS, BRAF and PIK3CA mutation detection kits are also SFDA-approved for clinical use in China and have CE marking for IVD use in Europe. Molecular tests for rearrangements of the ROS1 and RET genes, found in one percent to two percent of NSCLC, are currently in clinical trials in China, and will be submitted for CE marking and SFDA for approval later this year. The company's portfolio also includes gene expression

assays to predict chemotherapy response, including ERCC1 for platinum-based chemotherapy and RRM1 for gemcitabine therapy.

"Our goal is to provide a comprehensive panel of molecular tests that will quickly and reliably identify driver mutations in cancer tissue so that patients can receive the most appropriate treatment based on the mutation profile of their tumor," said Dr David Whyte, VP of Global Development, Amoy Diagnostics. "We believe firmly that real-time PCR is the technology of choice for therapeutic target identification, due to its ease of use and high sensitivity. In a matter of a few hours we can go from FFPE tissue to purified nucleic acid to actionable clinical information. This process can be readily scaled to include newly discovered driver mutations."

The assays are based on proprietary technology developed in Amoy Diagnostic's laboratory in Xiamen, China. The technology uses a patented two-step process to detect mutations in tumor nucleic acids. The method has excellent sensitivity and accuracy, and has been validated on PCR instruments from several manufacturers, including: Roche LightCycler 480; Stratagene Mx 3000P & 3005P; Applied Biosystems StepOnePlus, 7300, 7500 and 7900; Bio-Rad IQ5/CFX96; and the Qiagen Rotor-Gene Q. The kits are shipped via FedEx, DHL or other carriers to laboratories in over 30 countries.