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ASIA EDITION

FDA grants approval for Roche's ALK test as CDx for Zykadia

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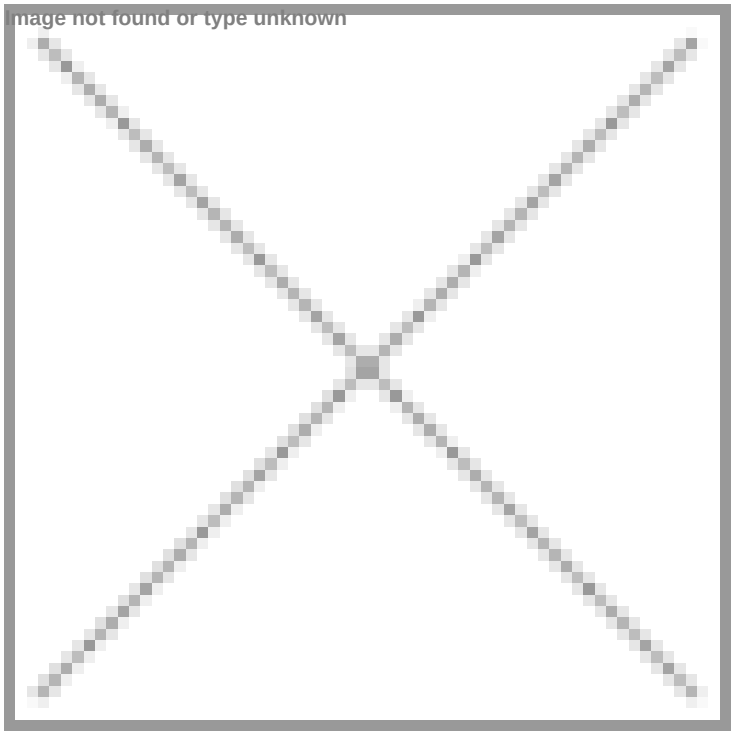

Singapore: The US FDA has granted approval for Roche's VENTANA ALK (D5F3) CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer (NSCLC) patients eligible for treatment with the Novartis drug ZYKADIA (ceritinib). Founded in 1896, Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

The VENTANA ALK (D5F3) Assay is the only immunohistochemistry (IHC) test approved by the FDA as a companion diagnostic for ZYKADIA. The VENTANA ALK (D5F3) CDx Assay is available for use on BenchMark IHC/ISH instruments. It is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib) or ZYKADIA® (ceritinib).

Nearly 1.6 mn people fall prey to lung cancer every year. It is one of the leading causes of cancer death in Asia.

Ann Costello, Head of Roche Tissue Diagnostics, said, "With the FDA's approval of the expanded use of the VENTANA ALK (D5F3) CDx Assay to determine which lung cancer patients are eligible for ZYKADIA, we are helping clinicians and their patients identify additional treatment options for non-small cell lung cancer. This is another example of Roche's continued

commitment to advancing the standard of care for lung cancer patients and personalized medicine."