

## Media Release

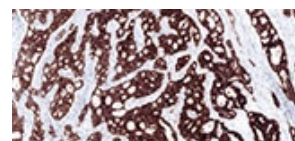
### Ventana receives FDA approval for the first fully automated IHC companion diagnostic to identify lung cancer patients eligible for XALKORI® (crizotinib)

**Tucson, AZ, June 15, 2015** - Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, today announced approval of the VENTANA ALK (D5F3) CDx Assay by the US Food and Drug Administration (FDA) as a companion diagnostic to aid in the identification of patients for Pfizer's FDA approved targeted therapy, XALKORI® (crizotinib). The VENTANA ALK Assay was approved as a CE-IVD in Europe in 2012 and was approved by the Chinese Food and Drug Administration (CFDA) in 2013. With this US FDA Class III approval, ALK IHC testing is now widely accessible on VENTANA BenchMark1 immunohistochemistry (IHC) instruments globally, can be easily integrated into standard lab workflow and offers fast test results with a binary, straightforward scoring method.

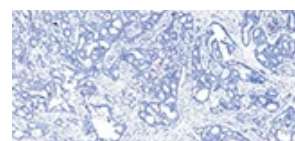
"FDA approval of the VENTANA ALK (D5F3) CDx Assay is a tremendous accomplishment," says Mary Padilla, MD Senior Director of Pathology and Medical Director for Ventana Companion Diagnostics. "The test provides physicians and patients a fast and accurate method to identify ALK protein expression, and clinicians can be confident knowing that our FDA approval is based on data resulting from collaboration between Ventana and Pfizer. Ventana used the VENTANA ALK (D5F3) CDx assay and scoring method to retrospectively test patient samples from Pfizer-sponsored clinical trials and demonstrated that the test is effective in identifying patients with ALK-positive NSCLC who may benefit from treatment with XALKORI® (crizotinib).

"The success of the VENTANA ALK (D5F3) CDx Assay is an excellent example of Roche's continued commitment to advancing the standard of care for patients," says Daniel Zabrowski, President of Roche Tissue Diagnostics (Ventana). "Traditional fluorescent in situ hybridization (FISH) ALK testing methods have required patients to wait weeks before receiving their ALK mutation status. With an approved ALK IHC test, physicians and their ALK positive patients now have the option to learn their ALK status and start an ALK-targeted therapy within days."

Lung cancer is the leading cause of cancer-related death worldwide and in the United States, with NSCLC being the most common sub-type. One important biomarker in NSCLC is the anaplastic lymphoma kinase (ALK) fusion gene, which is associated with pathologic expression of an ALK fusion protein. The detection of ALK positivity is very important for NSCLC patients because inhibition of the ALK tyrosine kinase has led to tumor shrinkage for ALK-positive patients. XALKORI® (crizotinib) is an oral first-in-class ALK inhibitor that has been shown to block important growth and survival pathways which may shrink or slow the growth of tumors. It is indicated for the treatment of patients with metastatic non-small cell



Positive case of lung tissue stained for ALK with VENTANA ALK (D5F3) CDx Assay



Negative case of lung tissue stained for ALK with VENTANA ALK (D5F3) CDx Assay



lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test <sup>2</sup>.

**Companion diagnostics (CDx)** are tests designed to confirm the presence of a specific biomarker to assist physicians in selecting effective therapies for their patients, based on the individual characteristics of each person. Incorporating a companion diagnostic strategy into a drug development program may expedite the drug approval process and help generate more effective treatments with improved safety profiles for patients.

<sup>1</sup>Available only on VENTANA BenchMark XT IHC/ISH staining instruments in the United States

<sup>2</sup>XALKORI® (crizotinib) Prescribing Information. New York, NY: Pfizer Labs; 2015

**Ventana Medical Systems, Inc.** ("VMSI") (SIX: RO, ROG; OTCQX:RHHBY), a member of the [Roche](#) Group, innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. VENTANA products are used in clinical histology and drug development research laboratories worldwide. The company's intuitive, integrated staining, workflow management platforms, and digital pathology solutions optimize laboratory efficiencies to help reduce errors, support diagnosis and enable informed treatment decisions by anatomic pathology professionals. Together with Roche, VMSI is driving [Personalized Healthcare](#) through accelerated drug discovery and the development of companion diagnostics to identify the patients most likely to respond favorably to specific therapies. Ventana Medical Systems, Inc.

#### About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-eight medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit [www.roche.com](http://www.roche.com).



VENTANA BenchMark XT IHC/ISH staining instrument



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