Media Release

Ventana seeks FDA premarket approval for ALK IHC companion diagnostic to benefit lung cancer patients

TUCSON, Ariz., January 21, 2015— Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, today announced its FDA submission for premarket approval (PMA) of the VENTANA ALK (D5F3) CDx Assay. The companion diagnostic (CDx) immunohistochemistry (IHC) test is designed to identify ALK[1]-positive lung cancer patients that may benefit from treatment with targeted therapy that inhibits the ALK gene. This submission was the fourth and final module and application required by the FDA's PMA process.

"Premarket approval of the VENTANA ALK (D5F3) CDx Assay will enable more lung cancer patients to access ALK gene testing and obtain faster test results over current FISH or molecular testing methods. We are very pleased about the potential impact of this important diagnostic in providing these patients access to drugs specifically designed to target the ALK mutation," said Doug Ward, Lifecycle Leader for Companion Diagnostics, Ventana Medical Systems, Inc.

"We're extremely pleased to have finalized the submission of the VENTANA ALK (D5F3) CDx Assay. PMA is the most stringent type of device marketing application required by the FDA. Our 4-step modular submission process for premarket approval is a major progression as it has enabled the FDA to review each module after submission and provide us with timely feedback. This helps mitigate potential delays early in the review process and ensures a more efficient and effective approval process," said Troy Quander, Vice President, Regulatory Affairs, Ventana Medical Systems, Inc.

Lung cancer is the leading cause of cancer-related deaths worldwide, with non-small cell lung cancer (NSCLC) being the most common sub-type. About 5% of NSCLC patients have been found to have a rearrangement in a gene called ALK. This change is most often seen in non-smokers (or light smokers) who have the adenocarcinoma subtype of NSCLC. The ALK gene rearrangement produces an abnormal ALK protein that causes the cells to grow and spread.[2] The new VENTANA ALK (D5F3) CDx Assay provides patients and their physicians a highly efficient, standardized, and cost effective testing method for the assessment of ALK protein expression and eligibility for available ALK inhibitor targeted therapy. IHC testing is widely accessible on VENTANA BenchMark XT instruments.

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. Since 2002, the company has worked with more than 45 biopharmaceutical partners and is currently engaged in more than 180 collaborative projects to develop and commercialize companion diagnostics globally.

[1] The official name of the ALK gene is 'anaplastic lymphoma receptor tyrosine kinase'
[2] Targeted therapies for non-small cell lung cancer, American Cancer Society website, last revised 12/12/2014

About Ventana Medical Systems, Inc.
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.

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