



# Ventana to collaborate with Pfizer and CST on companion diagnostic to identify lung cancer patients with ALK gene rearrangements

Tuesday, January 10, 2012 - 08:00am

Collaboration a significant step in the war against non-small cell lung cancer (NSCLC)

**Tucson, Jan 10, 2012** - Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, today announced that it has entered into a collaboration agreement with Pfizer Inc. and license agreement with Cell Signaling Technology (CST) to develop the first fully automated and standardized immunohistochemistry (IHC) companion diagnostic test for ALK gene rearrangements. Ventana will develop the test which is intended to identify non-small cell lung cancer (NSCLC) patients with anaplastic lymphoma receptor tyrosinekinase (ALK) gene rearrangements who may benefit from Pfizer's XALKORI® (crizotinib), approved in the US in August of 2011. The test will measure the associated protein product when an ALK gene rearrangement is present. This news comes on the heels of two separate companion diagnostic strategic collaborative agreements Ventana recently announced with Aeterna Zentaris GmbH and with Syndax Pharmaceuticals, Inc.

Under the terms of the agreements with Pfizer Inc. and CST, the VENTANA ALK IHC diagnostic test will be based on CST's D5F3 antibody and VENTANA Optiview DAB detection, for performance on VENTANA automated platforms.

"At Ventana our mission is to improve the lives of all patients afflicted with cancer," said Mara G. Aspinall, President of Ventana Medical Systems, Inc. "We believe this collaboration will provide enormous benefit to patients suffering from NSCLC through biomarker identification. Our early development data suggests that the combination of CST's D5F3 antibody and VENTANA OptiView detection generates a highly sensitive

assay that detects cases with very low expression of the ALK protein in lung tissue which means that XALKORI may be an appropriate treatment for those patients.”

NSCLC is the world’s number one cause of cancer related death, the most common form being adenocarcinoma. The determination of the presence of ALK gene rearrangements helps physicians select more specific therapies for NSCLC patients, including XALKORI. The benefits of IHC testing include laboratory workflow automation, speed, and cost effectiveness. The broad availability of IHC testing on VENTANA instruments will also benefit physicians and patients worldwide.

“In line with our vision for „Personalized Healthcare”, this agreement will help further our quest to be the companion diagnostics Partner of Choice to pharma companies worldwide,” adds Aspinall.

“We are delighted to collaborate with Ventana to develop an additional testing option to identify NSCLC patients with ALK gene rearrangements. Working with regulatory authorities, our goal is to help those patients and their physicians determine the treatment options available to them,” said Garry Nicholson, president and general manager, Pfizer Oncology. “Pfizer believes that each cancer patient’s tumor is genetically unique, and that biomarker testing helps to identify those patients who may benefit from therapy.”

“CST is very excited to enter into this agreement with Ventana for the development of next-generation diagnostic products that intend to fulfill the promise of personalized cancer medicine,” said Michael J. Comb, Ph.D., CST President and CEO. “CST and one of its partners own dominant rights to the intellectual property directed to the detection of EML4-ALK translocations. As a leader in the development and manufacture of high performance antibody products, we are thrilled that the strategic R&D and intellectual property investments we’ve made in the area of EML4-ALK translocation detection are being applied to significant unmet needs in the diagnosis and treatment of cancer patients.”

As new biomarker and diagnostic tests become increasingly available, they provide valuable information about potential recipients for these novel agents. Matching specific drugs to specific cancer types, or *fitting the treatment to the patients*, is at the heart of Roche’s scientific vision for “Personalized Healthcare”. It is the company’s highest priority now and in the future.

**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 solutions 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 reduce errors, support diagnosis and inform treatment decisions for anatomic pathology professionals. Together with Roche, VMSI is driving personalized medicine through accelerated drug discovery and the development of "companion diagnostics" to identify the patients most likely to respond favorably to specific therapies. Visit [www.ventana.com](http://www.ventana.com) to learn more. VENTANA, the VENTANA logo, and OptiView are trademarks of Roche. All other trademarks are the property of their respective owners.

**About Cell Signaling Technology, Inc.** Cell Signaling Technology, Inc. is dedicated to delivering the world's highest quality antibody products to accelerate progress in biological research and personalized medicine. Through its proprietary monoclonal antibody technology (XMT® ) and PTMSan® proteomics technology, CST continues to be at the forefront of applied systems biology research, promoting greater understanding of biochemical aberrations that underlie important diseases, including cancer. Cell Signaling Technology®, XMT®, and PTMSan® are trademarks of Cell Signaling Technology, Inc. For more information on CST visit [www.cellsignal.com](http://www.cellsignal.com).