Media Release

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Ventana Receives FDA Clearance for p53 (DO-7) Image Analysis and Digital Read Applications

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the VENTANA Companion Algorithm p53 (DO-7) image analysis application using the VENTANA iScan Coreo Au scanner and VIRTUOSO software. Currently, Ventana is the only company offering an FDA-cleared p53 image analysis algorithm for determining p53 expression levels in breast cancer patients. Ventana is offering the p53 (DO-7) image analysis algorithm in addition to the company's FDA-cleared algorithms for HER2 (4B5), PR (1E2), and Ki-67 (30-9).

"As a market leader and long-term innovator in anatomic pathology, Ventana is committed to improving the lives of cancer patients," says Mara G. Aspinall, President, Ventana Medical Systems, Inc. "We provide the most clinically-validated, FDA-cleared digital pathology algorithms in the market today. When you combine this with our broad portfolio of instruments and assays, and our expertise in laboratory knowledge management and workflow, it is clear that Ventana is positioned to deliver the most comprehensive digital pathology solutions available globally."

The p53 (DO-7) image analysis algorithm assists pathologists in the detection and semi-quantitative measurement of p53 (DO-7) protein in formalin-fixed, paraffin-embedded normal and neoplastic tissue. When the p53 (DO-7) algorithm is used in conjunction with the CONFIRM anti-p53 (DO-7) Primary Antibody, it may be used as an aid in the assessment of p53 expression in breast cancer patients (but is not the sole basis for treatment). The FDA clearance includes all of the components of the VENTANA laboratory workflow solution when used as a system, including the company's BenchMark XT slide stainer, p53 clone DO-7, iView and *ultra*View DAB detection systems, VENTANA iScan Coreo Au slide scanner, and Virtuoso image management software.

Steve Burnell, PhD, VP, Ventana Digital Pathology and Workflow states, "As is the case for Ki-67, Ventana is the only company offering a 510(k)-cleared algorithm for p53 today. Our increasing Companion Algorithm portfolio of FDA-cleared products is evidence both of our unique capabilities in this field as well as our commitment to empower our customers to deliver the highest standards of patient care through the most robust digital pathology solutions available."

In conjunction with this clearance, Ventana also received FDA clearance for the digital read application that allows pathologists to interpret p53 (DO-7) stained slides as images on a computer monitor using the iScan Coreo Au scanner with VIRTUOSO software.

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 Healthcare 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 to learn more.

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