Media Release

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Ventana Receives FDA Clearance for Progesterone Receptor (1E2) 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 Progesterone Receptor (PR) (1E2) image analysis application used with the VENTANA iScan Coreo Au scanner running VIRTUOSO software. This announcement comes on the heels of two other FDA clearances Ventana recently announced for the HER2 (4B5) and Ki-67 (30-9) image analysis and digital read applications.

The PR (1E2) image analysis algorithm assists pathologists in the detection and semi-quantitative measurement of PR expression in formalin-fixed, paraffin-embedded normal and neoplastic breast tissue. This application aids the pathologist in achieving consistency and objectivity in PR interpretation for breast cancer patients.

When the PR (1E2) algorithm is used in conjunction with the VENTANA CONFIRM anti-PR (1E2) Rabbit Monoclonal Primary Antibody, it may be used as an aid in the assessment of breast cancer patients for whom endocrine treatment is being considered but is not the sole basis for treatment. The FDA clearance includes all of the components of the VENTANA laboratory workflow solution including the company's BenchMark slide stainer, exclusive PR clone 1E2, detection systems, slide scanner, and image management software.

"The addition of the algorithm for PR (1E2) allows us to expand our Companion Algorithm image analysis offerings in the clinical market," said Dr. Steve Burnell, Vice President, Ventana Digital Pathology and Workflow. "This newest addition to the VENTANA complete digital pathology workflow solution will assist pathologists in generating consistent and objective results. It is another example of our commitment to delivering the highest standards of patient care through the most advanced digital pathology solutions available."

Simultaneously, Ventana received FDA clearance for the digital read application that allows pathologists to interpret PR (1E2) 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. VENTANA, the VENTANA logo, iScan, BenchMark and VIRTUOSO are trademarks of Roche.

VMSI Media Relations

Jacqueline Bucher
Director, Corporate Communications
Phone: 520-877-7288
e-mail: jacquie.bucher@ventana.roche.com