

Media Release

Tucson, Ariz, March 1, 2012

Ventana receives FDA approval of INFORM HER2 Dual ISH assay on the BenchMark ULTRA

Ventana Medical Systems, Inc. ([Ventana](#)), a member of the Roche Group, announced today that the FDA has approved the application of its [INFORM HER2 Dual ISH](#) DNA Probe cocktail assay (HER2 Dual ISH) on the VENTANA [BenchMark ULTRA](#) automated slide staining platform for commercialization in the United States. Originally approved by the FDA in June 2011 for use with the [BenchMark XT](#) instrument, the HER2 Dual ISH assay is now approved for use on both VENTANA BenchMark advanced staining platforms available in the U.S. The HER2 Dual ISH assay is intended for use in the determination of HER2 gene status in breast cancer tissue as an aid in the assessment of patients that may be considered for treatment with [Herceptin](#) (trastuzumab). Herceptin is clinically proven to improve outcomes for patients with HER2-positive breast cancer.

“The INFORM HER2 Dual ISH assay improves treatment of breast cancer patients by providing clinicians increased accuracy and faster time to result compared to fluorescent *in situ* hybridization (FISH) assays,” said Greg Yap, Lifecycle Leader, Advanced Staining Assays at Ventana. “In a Ventana clinical study comparing HER2 Dual ISH to FISH, our findings showed that more patients would have received the correct result and be identified as potential candidates for Herceptin therapy using our ISH test. In addition, FISH assays for gene amplification must be run manually by skilled technologists, making them labor-intensive and time consuming. The average turn-around time for HER2 FISH testing in breast tissue is 2-3 days as opposed to approximately 13 hours for HER2 Dual ISH testing. We are pleased to offer all of our customers and patients worldwide our HER2 Dual ISH assay with its benefits over traditional FISH testing.”

The HER2 Dual ISH assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope. Unlike FISH assays, the HER2 Dual ISH assay uses robust brightfield detection technology to deliver a result which may be easily interpreted by a pathologist as it allows them to screen the entire tissue sample for regions of HER2 gene amplification. In addition,

the signals don't fade over time so results can be stored and shared between pathologists for a more collaborative diagnosis.

Ventana offers a full suite of market leading¹ fully automated breast cancer diagnostic assays and digital pathology solutions to physicians and lab professionals globally. The HER2 Dual ISH assay combined with the [PATHWAY HER2 \(4B5\)](#) immunohistochemistry assay provides clinicians with highly accurate tools for determining a patient's HER2 status, enabling the physician and patient to move forward with a targeted treatment plan.

¹Ventana internal sales and market assessments, 2011

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, INFORM, PATHWAY, and BenchMark are trademarks of Roche.

VMSI Media Relations

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