Media Release

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Ventana Medical Systems, Inc. receives FDA approval for the first fully automated diagnostic assay for HER2 gene status determination in breast cancer patients

Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, announced today that the FDA approved the INFORM HER2 Dual ISH DNA Probe cocktail assay (HER2 Dual ISH) for commercialization in the United States. This is the first fully automated assay approved by the FDA for determination of HER2 gene status in breast cancer as an aid in the assessment of patients considered for treatment with Herceptin (trastuzumab).

For breast cancer patients, waiting days or even weeks for accurate test results can feel like an eternity. Clinicians and patients agree that a rapid, accurate diagnosis enabling them to move forward with a targeted treatment plan is critical. Defining HER2 status allows the treatment team to predict response to Herceptin therapy, which is clinically proven to improve outcomes for patients with HER2-positive breast cancer.

"Ventana and Roche are global leaders in companion diagnostics, including assays for predicting response to Herceptin." said Greg Yap, Ventana's Lifecycle Leader for Advanced Staining Assays. "FDA approval of the HER2 Dual ISH assay is an important milestone benefiting breast cancer patients and diagnostic providers in the U.S. The HER2 Dual ISH assay has been marketed outside the U.S. as a CE marked in vitro diagnostic since 2010 and has quickly become the market leader. Combined with our market-leading PATHWAY HER2 (4B5) immunohistochemistry assay and our complete suite of fully automated diagnostic solutions, we continue to innovate to advance breast cancer testing."

The Ventana HER2 Dual ISH assay transforms the diagnostic process by providing complete, walk-away automation on the VENTANA BenchMark XT instrument and dramatically reducing the turnaround time for accurate results. Today, many labs rely on fluorescent *in situ* hybridization (FISH) assays to test for HER2 gene amplification. These assays need to be run

manually by skilled technologists, making them extremely labor-intensive and time consuming.

The HER2 Dual ISH assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope. Unlike FISH assays, this robust brightfield detection technology delivers a result which is easily interpreted and produces signals that don't fade over time - allowing results to be stored and shared between pathologists.

"By having both signals visible on a single slide using light microscopy, we can determine the HER2 gene status within the morphological context of the tumor," said Eric Walk, M.D., Chief Medical Officer at Ventana. "We believe this adds significant medical value for the patient and is an important advance toward improved patient focused solutions."

About Ventana Medical Systems, Inc.

Ventana Medical Systems, Inc. develops, manufactures, and markets instrument/reagent systems that automate tissue preparation and slide staining in clinical histology and drug discovery laboratories worldwide. The company's Smart Systems for anatomic pathology are important tools used in the diagnosis and treatment of cancer and infectious diseases. Ventana drug discovery systems are used to accelerate the discovery of new drug targets and evaluate the safety of new drug compounds. In addition, the company offers premier workflow solutions designed to improve laboratory efficiency, providing safeguards to enhance the quality of healthcare. Ventana Medical Systems, Inc. is a wholly-owned member of the Roche Group. For more information on Ventana, visit www.ventana.com.

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