Media Release

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Early Adopter of INFORM HER2 Dual ISH Assay Optimistic about Impact on Patient Care, Hospital Bottom Line

University Medical Center in Tucson (UMC) is validating the VENTANA INFORM HER2 Dual ISH DNA Probe cocktail assay (HER2 Dual ISH) on the BenchMark XT automated slide staining instrument to help determine HER2 gene status in breast cancer patients in an effort to change the paradigm for targeted treatment therapies. The assay, developed by Ventana Medical Systems, Inc. (Ventana), a member of the Roche group, 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).

"We believe HER2 Dual ISH will be critical in dictating therapy and diagnostic decisions," said Dr. Jennifer Thorn, molecular pathologist and assistant professor of pathology at UMC and a member of the team validating HER2 Dual ISH. "We'll see turnaroundtime for test results shortened from four to seven days when outsourced to a different lab, to 48 to 72 hours when conducted here in our own lab. This means quicker diagnosis and therapeutic decisions, and better overall patient care."

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 that enables them to move forward with a targeted treatment plan is critical. The VENTANA HER2 Dual ISH assay provides complete, walk-away automation on the VENTANA BenchMark XT instrument, transforming the diagnostic process 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 must be run manually by skilled technologists, making them extremely labor-intensive and time consuming.

HER2 Dual ISH Technology; 'Adds Significant Medical Value for The Patient'

Breast cancer is the second leading cause of cancer-related death among women. An estimated 207,090 new cases of breast cancer were diagnosed in the United States during

2010 and close to 39,800 women died from the disease, according to the National Cancer Institute. About 20 percent of women diagnosed with breast cancer are HER2-positive.

The HER2 Dual ISH assay measures the number of copies of the HER2 gene in tumor tissue. Defining a patient's HER2 status allows the treatment team to predict response to Herceptin therapy, which has been clinically proven to improve outcomes for patients with HER2-positive breast cancer.

With the HER2 Dual ISH assay, the HER2 gene status is determined on a single slide using a standard light microscope. Unlike FISH assays, the HER2 Dual ISH assay uses robust brightfield detection technology to deliver results that are easily interpreted, and the signals do not fade over time. This allows the actual slides to be stored long term and easily shared between pathologists and oncologists.

"This new technology will impact our practice in many positive ways-- one of the most important is the ability to archive the slides," says Dr. Lauren LeBeau, UMC breast cancer specialist and assistant professor of pathology. "Using the HER2 Dual ISH assay, we can easily show the slides and share with the treatment team how and why we interpreted slides the way we did. We work with the oncologists to make critical diagnostic decisions, and being able to view all the information possible will lead to a greater continuity of patient care."

The FDA approval of HER2 Dual ISH in June of 2011 was based on a U.S. study involving tumor samples from 510 patients with breast cancer. This study showed that the test was effective in confirming that a patient's tumor sample contained more than the normal number of copies of the HER2 gene in 96 percent of the HER2-positive tumor samples. Patients with more than the normal number of HER2 gene copies are considered candidates for Herceptin therapy.

"HER2 by ISH method is the gold standard in determining HER2 amplification," says Dr. Erika Bracamonte, director of surgical pathology at UMC. "HER2 Dual ISH will allow our hospital to use our own lab, instruments and pathologists rather than outsourcing. ISH testing will be brought into the daily function of the laboratory, bringing additional revenue for the

healthcare center. Overall, this product is a win-win-win for patients, clinicians and the hospital."

"Ventana and Roche are global leaders in companion diagnostics, including assays for predicting response to Herceptin," said Greg Yap, Ventana 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, Ventana continues to innovate and advance breast cancer testing."

About University Medical Center:

University Medical Center is a 487-bed hospital in Tucson, Arizona. It is the flagship teaching hospital of the University of Arizona College of Medicine. UMC is a national leader in heart care, oncology, organ transplantation, trauma and pediatrics and has earned a spot among *US News & World Reports'* Best Hospitals every year for more than a decade. Its mission is to advance health and wellness through education, research and patient care.

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 "Smart Systems" – intuitive, integrated staining and workflow management platforms that 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 to learn more.

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