Media Release

World Health Organization recommends use of p16 IHC to help diagnose high-grade cervical disease

Tucson, AZ, August 29, 2014 -- Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, today announced that the World Health Organization (WHO) has issued new guidance recommending the use of p16 immunohistochemistry (IHC) testing to improve the detection of pre-cancerous cervical disease. In doing so, the WHO is the first global organization to issue written recommendations on the use of p16 after the College of American Pathologists (CAP) and the American Society for Colposcopy and Cervical Pathology (ASCCP) provided similar guidance in 2012.1, 2

Traditionally, the evaluation of cervical tissue samples has been performed using the slide-based hematoxylin and eosin (H&E) stain; however, this method of interpretation is subjective and diagnostic variability from pathologist to pathologist is well documented.3 In some cases this variability may lead to unnecessary procedures or even false negative results.

During the Roche Cervical Cancer Symposium to be held in London as part of the European Congress of Pathology (ECP), Dr. Teresa Darragh, Professor of Clinical Pathology at the University of California in San Francisco and former president of the American Society for Colposcopy and Cervical Pathology (ASCCP), and Dr, Karin Denton, Consultant Cytopathologist and Q. A. Director at North Bristol NHS Trust, Southmead Hospital, Bristol, U. K., will present findings from the latest studies.
demonstrating the enormous contribution that advanced p16 biomarker-based tests can make to women's health.

“p16 is overexpressed in tissue specimens with transforming HPV infections and has proven to be an extremely reliable and useful marker particularly in cervical histological diagnoses,” said Dr. Teresa Darragh. “Biomarkers such as p16 help give objective evidence to support our H&E diagnoses. They add ‘science’ to the morphological ‘art’ of interpretation.”

Dr. Christine Bergeron, Director of Pathology and Cytology at Laboratoire Cerba and co-author of the WHO recommendations, explains “Diagnostic studies have demonstrated that the use of p16 immunohistochemistry substantially improves the reproducibility and accuracy of (histopathologic) diagnoses. The adoption of the WHO recommendations and the use of p16 IHC will help address the substantial diagnostic variability present today. This will truly benefit the patient as this will help reduce unnecessary treatment but also help identify those women that should be treated.”

“Cervical cancer is virtually preventable through screening and treatment of precancerous lesions, yet it remains the third most common cancer in women worldwide,” said Ann Costello, VP, Lifecycle Leader for Advanced Staining Assays, Ventana Medical Systems, Inc. “The recent recommendations from the WHO further validate Roche’s commitment to enhance cervical cancer screening and diagnosis for the improvement of women’s health.”

About Roche’s cervical cancer portfolio

The cobas® HPV Test screens for all high-risk genotypes together while simultaneously identifying those women who are genotype 16 and/or 18 positive that would benefit from immediate intervention. The CINtec® PLUS Cytology* test helps identify underlying disease, determining those who should proceed to colposcopy. The CINtec® p16 Histology test helps pathologists accurately confirm the presence or absence of cervical pre-cancer in cervical biopsy samples to help clinicians make informed decisions about patient follow up or treatment.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and
neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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 products 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 help reduce errors, support diagnosis and enable informed treatment decisions by 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.

* The CINtec® PLUS Cytology Kit is not available in all geographies and/or may not be approved for all uses discussed in this press release. It is currently not available for use in the United States.

** In the US, the CINtec® p16 Histology product is available as a Class 1 IVD without diagnostic claims. The utility, as described in this press release and as recommended by the cited WHO and CAP/ASCCP recommendations, has not been cleared or approved by the United States Federal Food and Drug Administration. CINtec® p16 Histology is intended for use with the VENTANA BenchMark ULTRA, BenchMark XT, and BenchMark GX*** instruments using VENTANA OptiView DAB IHC or ultraView DAB detection.

***The BenchMark GX IHC/ISH instrument is not available in the United States.

References

