

Basel, 19 July 2011

## **Roche acquires mtm laboratories AG, expanding offering in cervical cancer testing**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has signed an agreement under which it will acquire 100 percent of mtm laboratories AG (mtm), a privately-held company based in Heidelberg, Germany. mtm is a global leader in developing in vitro diagnostics with a focus on early detection and diagnosis of cervical cancer, the largest early detection market in oncology. mtm will become part of Roche's Tissue Diagnostics (Ventana Medical Systems, Inc.) business unit. Under the terms of the agreement, Roche will pay mtm shareholders an upfront payment of approximately 130 million EUR as well as up to approximately 60 million EUR upon reaching performance-related milestones. The transaction is subject to customary closing conditions and is expected to close in the coming weeks.

“Pathologists increasingly rely on the rapid and successful identification and clinical validation of molecular markers associated with cervical cancer,” said Daniel O’Day, COO Roche Diagnostics. “mtm products are highly complementary to Roche’s innovative cobas Human Papilloma Virus (HPV) assay for cervical cancer screening, which was launched in the US in April of this year. As a result of the acquisition, Roche will have a comprehensive portfolio offering for cervical cancer testing from cytological screening to histological diagnosis and provide previously unavailable levels of medical value to gynecologists and patients worldwide.”

mtm’s proprietary test solutions are based on the p16 biomarker and have been developed for the identification and diagnosis of pre-cancerous cervical lesions. p16, a gene involved in tumor suppression in the cell, is an established marker of the early oncogenic process leading to cancer. The level of p16 protein becomes markedly increased after persistent HPV infection leads to oncogenic transformation of cells in the cervix.

The mtm CINtec Plus Cytology kit is approved for use in Europe to identify over-expression of p16 in cervical Pap test samples to detect pre-cancerous lesions. This could aid in the classification of patients with abnormal Pap or positive HPV results into those with and without significant pre-cancer or cancer, reducing

unnecessary biopsies and ensuring patients are treated appropriately. CINtec Plus broadens the Roche solution in cervical cancer testing, in addition to the cobas HPV assay, both approaches may provide discrete and complementary benefits to patient management.

mtm's second product, CINtec Histology detects over-expression of p16 and is used in conjunction with traditional staining techniques to aid in the identification of high-grade cervical intraepithelial neoplasia (CIN) and cervical carcinoma in biopsy samples. This assay complements Roche's current market-leading menu of tissue-based cancer diagnostics.

"The combination of cobas HPV and p16 tests may redefine the standard of care for cervical cancer testing by improving detection, reducing unnecessary cervical biopsies, and improving the confirmation of cervical pre-cancer," added O'Day. "This comprehensive offering is unmatched in the diagnostics industry and will give Roche a superior competitive position in the field of cervical cancer testing."

"With its leadership position in the area of in vitro diagnostics and its global reach, Roche is the ideal company to accelerate adoption of next generation p16-based tests, which offer the promise to vastly improve the prevention of cervical cancer," commented Bob Silverman, CEO, mtm laboratories AG. "We're very excited about the future success of our products and pipeline as part of the Roche family."

In addition to p16's benefit to cervical cancer testing, p16 has been reported to have emerging clinical utility in other cancers, including anogenital cancers, head and neck cancer, lung cancer, and breast cancer.

### **CINtec *PLUS* Cytology and CINtec Histology**

The CINtec Plus Cytology kit is approved for use in Europe to identify p16 and Ki-67 proteins in cervical Pap test samples. In the US, CINtec PLUS is available for research use only. Roche will seek US FDA pre-market approval (PMA) based on planned clinical trials.

The CINtec Histology Kit is available worldwide as an IVD product (class I IVD in the US) for qualitative detection of p16 antigens in cervical biopsies. US FDA pre-market approval (PMA) is in the planning phases.

### **About mtm laboratories AG**

mtm laboratories AG is an ISO 9001 and ISO 13485 certified developer and manufacturer of In-Vitro Diagnostic Devices (IVDD) for use in the early detection and diagnosis of cervical cancer. The Company

operates on a global basis with headquarters in Heidelberg, Germany and subsidiaries in the United States, France, Italy and Spain. Further information can be found at: [www.mtmlabs.com](http://www.mtmlabs.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 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](http://www.ventana.com) to learn more.

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### **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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80’000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: [www.roche.com](http://www.roche.com).

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