



Press Release

Studies presented at EUROGIN highlight potential of p16INK4a as biomarker for screening and diagnosis of cervical cancer

Biomarker used in mtm diagnostic and screening assays evaluated in more than 20 presentations at leading women's reproductive health meeting

Heidelberg, Germany; May 5, 2006. mtm laboratories today announced that more than 20 studies evaluating p16INK4a as a potential marker for cervical cancer screening and diagnosis were presented last week at the 6th International Congress on "Human Papillomavirus Infection and Global Prevention of Cervical Cancer", organized by the European Research Organization on Genital Infection and Neoplasia (EUROGIN) in Paris. This research, conducted at a variety of medical and academic institutions, investigated the utility of p16INK4a - a biomarker central to diagnostic and screening technologies being developed by mtm laboratories for cervical cancer.

Several studies presented at the meeting evaluated the potential use of the CINtec® p16INK4a-based immunocytochemistry protocol on cervical cytology preparations. The results from these studies indicate the high potential of p16INK4a-based tests being developed into efficient diagnostic tools for the triage of abnormal Pap cytology results. In a presentation by Dr. Thomas Wright, MD, Professor of the Division of Gynecologic Pathology College of Physicians and Surgeons at Columbia University in New York, and titled "Improving the histological diagnosis of CIN2, 3 through the use of p16 immunohistochemistry", the relevance of an accurate histological diagnosis for the performance evaluation of novel tests and screening approaches for cervical cancer was highlighted. Two presentations given by K. Ulrich Petry, MD, Professor for Gynecology, Klinikum Wolfsburg, Germany, and by Nicolas Wentzensen, MD, University of Heidelberg, reported initial results from prospective multicenter clinical research studies performed in various colposcopy clinics, suggesting the potential of a novel p16INK4a ELISA-based approaches currently developed by mtm for the identification of biopsy-confirmed high-grade dysplastic lesions with a high sensitivity.

"We are encouraged by the large number of scientific presentations presented at the conference evaluating the potential of p16INK4a as a key biomarker for cervical disease," said Peter Pack, Chief Executive Officer for mtm laboratories. "Once again the large potential of products that are based on our proprietary p16INK4a technology has been validated by the various scientific reports. We are prepared to enter into pivotal trials demonstrating the clinical utility of our in vitro diagnostic products based on the p16INK4a marker for the use in cervical cancer screening and diagnosis."

Worldwide, cervical cancer is the second most common cancer in women, a position it shares with colorectal cancer. Globally, about 500,000 new cases of cervical cancer are diagnosed annually, and are associated with over 200,000 deaths. Prevention of cervical cancer is fundamentally tied to the early detection of the disease at the stage of pre-cursor lesions. If diagnosed early, cervical cancer can be virtually 100% prevented. However, current screening technologies and diagnostics for cervical cancer have well recognized limitations, resulting in substantial numbers of false negative and false positive test results. This is because current tests have a high degree of subjectivity and do not actually detect direct disease markers. There is a significant clinical need for an approach that detects a direct marker of disease accurately and quickly. mtm is developing such a family of screening and diagnostic technologies based on the p16INK4a biomarker. Diagnostics and screening technologies based on this marker promise extreme precision allowing for confident and accurate early diagnosis of disease.

mtm laboratories AG is a privately held company based in Heidelberg, Germany with a wholly owned subsidiary in Westborough (MA), USA. The ISO 9001 and ISO 13485 certified company develops In Vitro Diagnostic test systems for the early detection and diagnosis of cancer with a focus on cervical cancer screening, the largest screening market in oncology. Based on mtm's proprietary p16INK4a biomarker, the Company is in the process of developing and clinically validating cell-based CINtec® assays as well as non cell-based IVD products.