mtm laboratories Extends Series C Financing Round by EUR 7 Million ($9.7 Million)

There are no translations available.

Heidelberg, Germany; November 8, 2010- mtm laboratories, a privately held diagnostics company developing, manufacturing and globally commercializing in vitro diagnostics for cervical cancer early detection and diagnosis, today announced the signing for an additional tranche of Euro 7 million to its Series C funding. This addition is a formal expansion of the Company's last Series C in October 2009, and increases the total for the round to Euro 46 million (USD 63 million) in equity.

This completed Series C financing was led by three existing investors for mtm; HBM BioVentures Ltd, Wellington Partners, Gilde Healthcare Partners, with a consortium which included National Technology Enterprises Company, Heidelberg Innovation, and private investors.
Bob Silverman, Chief Executive Officer of mtm laboratories, commented:
"This additional tranche of financing supports the continued investment the Company is making into clinical trials and commercialization. We plan to use a large component of the proceeds of this financing to fund our United States regulatory trial for CINtec® PLUS Cytology that would support a PMA application."
mtm launched CINtec® PLUS Cytology (dual staining for p16 and Ki-67) in Europe in March, 2010. The product has been evaluated in 3 large European clinical trials in over 32,000 women. The significant results achieved in these trials demonstrate that CINtec® PLUS Cytology delivers both high sensitivity and high specificity for underlying cervical disease. These trials support a CE Mark with claims for 1) primary screening, 2) the triage of ASC-US and LSIL cytology results, and 3) the management of HR-HPV positive results when the Pap test is negative.

The basis of mtm's IVD products, the proprietary p16INK4a biomarker, is strongly over-expressed in pre-cancerous and cancerous cells of the cervix. Screening and diagnostic tools based on this biomarker are developed to improve the accuracy and efficiency for the screening and early diagnosis of cervical cancer. mtm's CINtec® in vitro diagnostic products focus on the detection of p16INK4a over-expression in biopsies (CINtec® Histology) and cervical cytology specimens (CINtec® PLUS Cytology).

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 is headquartered in Heidelberg, Germany but operates on a global basis and has subsidiaries in the United States, France, Italy and Spain. Further information can be found at: www.mtmlabs.com.

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Notes for editors

CINtec® PLUS Cytology

CINtec® PLUS Cytology is a screening and diagnostic tool combining high sensitivity and high specificity for detecting high-grade cervical disease in a single test. The CINtec® PLUS kit detects and stains for two biomarkers: the multiply validated cell cycle regulatory protein p16INK4a (p16) and Ki-67, a marker of active cell proliferation. Clinical trials involving over 32,000 women have demonstrated that when used together, this biomarker combination is both highly sensitive and highly specific to identify those women most likely to have existing high–grade disease. Moreover, the CINtec® PLUS test is independent of age and HR-HPV type of infection.

Applied in combination the co-detection of p16 plus Ki-67 in the same cell serves as an indicator of cell cycle de-regulation that occurs during HR-HPV induced oncogenic transformation and provides an objective criterion to identify those women who are likely to harbor high-grade disease. CINtec® PLUS can be applied on conventional and liquid based cytology slides. Double immuno-reactive (or: Dual-stained) cells in cytology are positively stained for both proteins:

- Brown cellular staining indicates p16 over-expression
- Red nuclear staining indicates Ki-67 expression

In the US these products are available as Class 1 IVDs without claims. The clinical performance, as described in this press release and as investigated in the cited studies, have not been cleared or approved by the United States Federal Food and Drug Administration.