



MDxHealth's ConfirmMDx® Meets All Primary Endpoints in Blinded U.S. Clinical Validation Study

IRVINE, CA, and HERSTAL, BELGIUM – 8:00 AM, October 7, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to improve the diagnosis and treatment of cancer patients, today announced that its ConfirmMDx for Prostate Cancer test met all of the primary endpoints in the recently completed multicenter, blinded DOCUMENT (Detection of Cancer Using Methylated Events in Negative Tissue) clinical validation trial. Preliminary analysis of data verifies the test's high negative predictive value (NPV) for ruling out the presence of prostate cancer and is a significant, independent predictor of risk for men being considered for repeat biopsy.

"This validation study confirms the high negative predictive value of the ConfirmMDx test in a U.S. population," says Wim van Criekinge, Ph.D., Professor at The University of Ghent and Chief Scientific Officer for MDxHealth. "The clinical utility of this test lies in its ability to reduce unnecessary repeat biopsies, improving patient care and optimizing limited healthcare resources."

ConfirmMDx for Prostate Cancer is a non-invasive test performed on the residual prostate tissues from the previous negative biopsy, providing critical epigenetic insights beyond histopathology alone, to enable more informed patient management decisions. The multicenter DOCUMENT study was conducted at five major U.S. urologic centers. The study involved analyzing tissue from initial negative biopsies and comparing assay results to cancer detection in subsequent biopsies within 24 months. ConfirmMDx for Prostate Cancer was used to analyze the epigenetic profile of prostate biopsy cores from 350 men screened by PSA. Results from the DOCUMENT study will be published after full analysis of the data is completed.

"We are extremely pleased with these results, demonstrating that ConfirmMDx for Prostate Cancer validates as a significant, independent predictor for the presence of prostate cancer in a repeat biopsy," said Dr. Jan Groen, CEO of MDxHealth. "These findings are consistent with the results from our earlier European clinical validation study that demonstrated a NPV of 90% (95% CI, 86-94%)."

About ConfirmMDx for Prostate Cancer

Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25-35% of those men receive false-negative results. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of occult cancer, leading to a high rate of repeat biopsies, often on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx for Prostate Cancer is able to detect an epigenetic field effect or 'halo' associated with the cancerization process at the DNA level. This "halo" around a cancer lesion can be present despite cells having a normal appearance under the microscope. Thus ConfirmMDx for Prostate Cancer aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure.

About MDxHealth

MDxHealth is a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment. The company's tests are based on proprietary gene methylation (epigenetics) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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