

NEWS RELEASE

REGULATED INFORMATION

MDxHealth's SelectMDx Study Published in European Urology

Data validates 'liquid biopsy' test's ability to identify men at risk for aggressive cancer

IRVINE, CA, and HERSTAL, BELGIUM – April 25, 2016 – <u>MDxHealth</u> SA (Euronext: MDXH.BR), today announced that data validating the clinical performance of the SelectMDx[™] for Prostate Cancer test have been published in European Urology.

The study, conducted across six institutions in The Netherlands, was designed to identify methods to improve the detection of clinically significant or aggressive prostate cancer at an early, more treatable stage. Researchers believe that both over-diagnosis and overtreatment of indolent, non-lethal prostate cancer could be reduced if specific biomarkers, which accurately identify men with aggressive tumors, could be used to guide the decision to conduct a biopsy.

Urine samples from two prospective, multicenter studies (n=905) were collected after digital rectal examination (DRE) to measure the mRNA expression levels of the SelectMDx genes, which were previously identified for their ability to specifically detect aggressive prostate cancer. These results were combined with standard clinical risk factors, i.e. DRE, PSA, PSA density, age and family and biopsy history to further improve patient stratification. An algorithm was developed in a training cohort, and successfully validated in an independent cohort. The SelectMDx risk score resulted in an improved identification of men at risk for harboring aggressive prostate cancer, significantly outperforming PSA and *PCA3*, with an area under the curve (AUC) of 0.90, and a negative predictive value (NPV) of 98% for clinically significant prostate cancer. In addition, SelectMDx resulted in the highest reduction of unnecessary biopsies in men with no or indolent prostate cancer.

"The SelectMDx test will help urologists identify men at very low risk for aggressive disease, who may avoid an unnecessary invasive biopsy procedure," reported Dr. Jack Schalken, Professor of Experimental Urology at the Radboud Medical Center in Nijmegen, The Netherlands. "The test also helps to improve patient selection for biopsy by indicating a patient's individual risk for aggressive, potentially lethal cancer."

"We have witnessed a paradigm shift in the management of prostate cancer over the past decade, with a focus on early detection and treatment of men with aggressive disease," **continued Dr. Schalken.** "However most experts agree that we need to minimize the diagnosis and overtreatment of men with indolent, non-lethal disease. Why saddle a man with the anxiety associated with a diagnosis of cancer if you do not intend to treat him?"

"Publication of this pivotal multicenter validation study in *European Urology*, the highest ranked medical journal in the field of urology, illustrates the significance of these data," **stated Dr. Jan Groen, CEO of MDxHealth**. "In a head-to-head prospective comparison, the SelectMDx test outperformed PSA as well as *PCA3*, another commonly used biomarker, and sets a new performance standard for non-invasive 'liquid biopsy' tests for use in the detection of clinically significant prostate cancer."

About SelectMDx™ for Prostate Cancer

Of the nearly 2 million prostate biopsies performed each year, less than a third find cancer. Most of these men could have avoided a painful and invasive prostate biopsy procedure, with its associated complications and costs. SelectMDx for Prostate Cancer is a proprietary urine-based,

molecular diagnostic test that offers a non-invasive 'liquid biopsy' method to assess a man's risk for prostate cancer. SelectMDx helps identify men at increased risk of harbouring aggressive, potentially lethal, prostate cancer who may benefit most from a prostate biopsy and earlier detection. The test delivers a negative predictive value (NPV) of 98% for clinically significant disease, helping to reduce unnecessary MRI procedures and invasive prostate biopsies by approximately 50%, thereby reducing healthcare costs.

About MDxHealth®

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) and other molecular technologies 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.

For more information:

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