

MDxHealth Announces Positive Clinical Updates for ConfirmMDx

ConfirmMDx included in the 2018 EAU Guidelines for Prostate Cancer

Publication of ConfirmMDx Validation Study in African American Men

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, April 26, 2018 - MDxHealth SA (Euronext: MDXH.BR) today announces two positive clinical developments for its ConfirmMDx® for prostate cancer test.

In line with its strategy to drive greater adoption, MDxHealth is pleased to announce the inclusion of ConfirmMDx in the 2018 European Association of Urology (EAU) guidelines. The EAU guidelines assist clinicians in making informed treatment decisions, taking into account the available scientific data. The inclusion of ConfirmMDx in the EAU guidelines will facilitate adoption of the test in EU member State-specific guidelines. Recently, urologists in several European countries have expressed interest in ConfirmMDx, and the Company has decided to pursue CE marking to enable sale of the test in Europe through selected partners.

The company completed a multicenter validation study demonstrating the utility of ConfirmMDx in African American men at risk of aggressive cancer missed by prostate biopsy. The paper entitled "Evaluation of an Epigenetic Assay for Predicting Repeat Prostate Biopsy Outcome in African American Men" was published in the journal *Urology* ([The Gold Journal](#)).

The study population consisted of 211 African American men from seven urology centers across the U.S. ConfirmMDx was shown to successfully identify African American men who had received false-negative biopsy results. Upon repeat biopsy, 38% of subjects with a previous negative diagnosis were diagnosed with prostate cancer, of which 33% were harboring high-grade disease (Gleason Score ≥ 7). Importantly, ConfirmMDx's clinical performance was equivalent to published studies that were conducted in primarily Caucasian populations. When the test was negative, it yielded a 94% negative predictive value for ruling out aggressive prostate cancer, consistent with previously reported results.

"African American men have the highest incidence of prostate cancer and are roughly 1.6 times more likely to develop the disease than Caucasians and 2.7 times more likely than Asian Americans, because their cancer behaves differently on a molecular level, we do not yet have a tool to safeguard against potentially fatal false-negative results," **said Dr. Robert Waterhouse MD, study investigator and urologist at Consortium on Disparities in Urologic Conditions, Memphis, Tennessee, US.** "The findings from this study are critical because they demonstrate the applicability of this test for this high-risk population who may harbor more aggressive disease. It's encouraging that ConfirmMDx provides consistently accurate results across ethnic groups."

"This study clearly demonstrates that ConfirmMDx is a valuable tool for the risk stratification of African Americans, who have a greater risk for aggressive prostate cancer," **said Dr. Jan Groen, CEO of MDxHealth.** "Moreover, inclusion of ConfirmMDx in the EAU guidelines is another important milestone for MDxHealth, and provides further recognition of the test's clinical value."

About ConfirmMDx for Prostate Cancer

ConfirmMDx for Prostate Cancer is the first epigenetic, and only tissue-based test in the 2016 NCCN Guidelines for early detection of prostate cancer which addresses false negative biopsy concerns. It is the only molecular diagnostic test that provides a very high negative predictive value (NPV) of 96% for clinically significant prostate cancers, and 90% NPV for all prostate cancers, as well as prostate mapping of the test results to help guide repeat biopsies. Each year, more than 1 million American

men undergo an invasive prostate biopsy with a negative result, however approximately 30% of those men have prostate cancer. The current standard of care for prostate biopsy procedures samples less than 1% of the prostate, leaving men at risk for undetected cancer and leading to a high rate of repeat biopsies, even on cancer-free men. ConfirmMDx for Prostate Cancer helps urologists identify low-risk men who may forego an unnecessary repeat biopsy and high-risk men who may benefit from intervention. ConfirmMDx has qualified for Medicare reimbursement and covered by numerous private health insurance plans.

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 genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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