

MDxHealth Reports 10-Fold Reduction of Repeat Prostate Biopsies in ConfirmMDx Clinical Utility Study

Results Published in *American Health and Drug Benefits*

IRVINE, CA, and HERSTAL, BELGIUM – May 20, 2014 – 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 the results of the ConfirmMDx[®] for Prostate Cancer clinical utility study will be published in the journal *American Health and Drug Benefits* (2014;7(3):129-134: www.AHDBonline.com). The study demonstrated a 10-fold reduction in the repeat biopsy rate in the ConfirmMDx-negative patient cohort as compared to the reported rate of repeat biopsy under the current standard of care.

"The urology community grapples with the management of patients presenting with clinical risk factors for prostate cancer, but who have a negative prostate biopsy. This study clearly shows the clinical value of the ConfirmMDx for Prostate Cancer test to aid in patient stratification and treatment decision making," stated investigator Jeffrey D. Small, MD, a practicing urologist with Yale New Haven Health System at Bridgeport Hospital. "The test, combined with other known risk factors, helps urologists identify men who may avoid unnecessary repeat prostate biopsies, and provides patients with greater peace of mind."

"These new data reinforce the clinical utility of ConfirmMDx to aid urologists in identifying men at sufficiently low risk for undetected prostate cancer who may avoid repeat biopsies," stated principle investigator on the study, Kirk J. Wojno MD, Head of Pathology at Comprehensive Medical Center in Royal Oak, Michigan. "ConfirmMDx represents an important advance in personalized medicine, improving upon existing clinical risk factors; these data illustrate that urologists have the confidence in ConfirmMDx test results to change treatment decisions."

"The publication of our clinical utility study data, as well as the multicenter DOCUMENT clinical validation study presented yesterday at the American Urology Association Annual Meeting in Orlando, Florida, are very important milestones in our managed care and reimbursement strategy," said Dr. Jan Groen CEO of MDxHealth. "These additional studies build upon our strong foundation of evidence for ConfirmMDx, and demonstrate the value of the test, both clinically and economically, to both urologists as well as health insurance payors and Medicare."

Study Details

The ConfirmMDx for Prostate Cancer test has been validated in blinded multicenter studies showing superior negative predictive value over standard histopathology for cancer detection in prostate biopsies. The study was designed to evaluate the impact of a ConfirmMDx-negative test result on the urologist's decision for repeat prostate biopsy. Five clinical urology practices that had ordered ConfirmMDx on a minimum of 40 patients with previous, cancer-negative biopsies over the course of the previous 18 months participated in the study. The repeat biopsy rate for all 138 men in this cohort receiving a negative ConfirmMDx result (i.e., reporting no epigenetic abnormalities) was <5%, demonstrating a 10-fold reduction from the reported rate of repeat prostate biopsy, which is greater than

40% (Pinsky et al, *BJUI* 2007). Repeat biopsies were performed on 6 of the 138 ConfirmMDx-negative patients (4.35%), and importantly no evidence of prostate cancer was found in those men.

About ConfirmMDx® for Prostate Cancer

Over 975,000 American men receive a negative prostate biopsy result each year, though approximately 25% of these men may still harbor occult prostate cancer. This well-documented risk of undetected cancer, often with clinically significant Gleason scores, leads to a high rate of repeat biopsies with greater than 40% of men receiving at least one repeat biopsy, and many receiving a 3rd and 4th biopsy. Today's gold standard diagnostic approach is the prostate biopsy procedure, collecting 10-12 needle core biopsy samples; however this sampling represents less than 1% of a man's prostate. ConfirmMDx for Prostate Cancer is an epigenetic assay to help urologists distinguish patients who have a true-negative biopsy from those at risk for occult cancer. The test is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This molecular "halo" around a cancer lesion can be present despite having a normal appearance under the microscope. The test helps urologists rule out prostate cancer-free men from undergoing unnecessary repeat biopsies and rule in high-risk patients who may require repeat biopsies and potential treatment. Performance of the proprietary ConfirmMDx genes and technology has been published in 42 studies with over 4,100 patients tested.

About MDxHealth

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain, bladder and lung cancers. For more information visit www.mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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