

MDxHealth Announces Positive Data Supporting Expanded Diagnostic Application for ConfirmMDx for Prostate Cancer

*Data Presented at the Annual Genitourinary Cancers Symposium
in San Francisco, January 7-9 2016*

IRVINE, CA, and HERSTAL, BELGIUM – January 11, 2016 - MDxHealth SA (Euronext: MDXH.BR) announced positive data today from two abstracts demonstrating the prognostic value of its ConfirmMDx® for Prostate Cancer test at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 7-9 January 2016 in San Francisco. The data, presented in two separate poster presentations demonstrate:

- ConfirmMDx test's ability to detect an epigenetic field effect associated with the presence of anterior-predominant tumors that was missed in a previous negative biopsy.
- ConfirmMDx test's ability to identify patients likely to harbor clinically significant prostate cancer from negative biopsy tissue. In histopathology positive biopsies the test showed a better separation between men with aggressive prostate cancer from those men with indolent disease.

Further details of the studies can be found below.

Ability of an Epigenetic Assay to Identify Anterior Prostate Tumors Based on a Negative 12-core Biopsy

There is increasing awareness that anterior-predominant prostate cancers (PCa) are poorly sampled by 12-core transrectal ultrasound-guided (TRUS) prostate needle biopsies. Approximately one-fifth of all prostate tumors occur in this area, and many are high grade and extend beyond the prostatic capsule.

Seven patients, with at least one prior negative TRUS biopsy, were subsequently diagnosed with anterior-only PCa based on a transperineal mapping template prostate biopsy (MTPB). Among these, six (86%) were methylation positive at initial biopsy, suggesting that the field effect from these anterior-predominant PCa extends to the region of TRUS biopsy sampling.

"Although a small study, this is a unique cohort who underwent extensive sampling at re-biopsy that confirmed the presence of an anterior-predominant tumor" **stated Todd Morgan M.D. Assistant Professor of Urology** and urological surgeon at the University of

Michigan, Ann Arbor, Michigan. "These results indicate that an epigenetic assay may be valuable even in patients with negative posteriorly-directed TRUS biopsies to detected anterior-predominant PCa."

MDxHealth's ConfirmMDx® Stratifies Patients for High-Grade Disease

Previous diagnostic studies have established the utility of ConfirmMDx as a significant, independent predictor of prostate cancer, with a negative predictive value (NPV) of 90% for all cancers, and a NPV of 96% for significant cancers. These data further validate the prognostic value of ConfirmMDx.

A training cohort of methylation-positive men with a negative index biopsy followed by either a Gleason score (GS) ≥ 7 (n = 43) or cancer-negative (n = 226) repeat biopsy was evaluated. Using the initial negative biopsy, men were stratified for the likelihood of harboring high-grade PCa focusing on a methylation intensity algorithm involving GSTP1, RASSF1 and APC. This algorithm was validated in a cohort of 102 men, with either a PCa-free (n = 20), GS6 (n = 46), or GS ≥ 7 (n = 36) biopsy.

"Based on the results of this study, we can identify patients likely to harbor clinically significant cancer in PCa-negative biopsies that is strongly correlated with the GS of PCa-positive biopsies. The risk score could better stratify men for the need for repeat biopsy and the risk of harboring occult clinically significant PCa" **stated Philip Ginsburg M.D., CMO of MDxHealth** "This additional actionable information from ConfirmMDx will provide urologists with enhanced diagnostic, prognostic and clinical guidance to help manage their patients."

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 undetected cancer, leading to a high rate of repeat biopsies, even 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. Performance of the proprietary ConfirmMDx genes and technology has been published in 45 studies on over 5,000 patients tested. The ConfirmMDx test has qualified for Medicare reimbursement as of November 3, 2014 and is also available to more than 152 million insured lives via 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 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.

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