



## **MDxHealth Announces Results from the ConfirmMDx™ for Prostate Cancer Test Studies Presented at the 2013 ASCO Genitourinary Cancers Symposium**

**IRVINE, CA, and LIEGE, BELGIUM** – February 18, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support the diagnosis and treatment of cancer patients, today announced the results of two studies of the ConfirmMDx™ for Prostate Cancer test presented at the ASCO Genitourinary Cancers Symposium 2013, February 14-16, Orlando, Florida, USA.

"These additional clinical studies add to our extensive body of peer-reviewed evidence, clearly demonstrating the ability of ConfirmMDx for Prostate Cancer test to provide valuable diagnostic information to support urologists in better patient management," said Jesse Savala, M.D., clinical pathologist and Medical Director at MDxHealth. "With the advances being made in human epigenetics, we believe that DNA methylation-based tests hold the promise to improve the diagnosis and subsequent treatment of cancer patients."

**Studies clearly show that the ConfirmMDx™ for Prostate Cancer test provides very important personalized information that cannot be achieved with traditional procedures:**

- In the Epigenetic Field Effect study in Histologically Benign Prostate Biopsy Cores it was shown that *GSTP1*, *APC* and/or *RASSF1* gene promoter methylation is more prevalent in histologically benign cores from prostate cancer (PCa) patients diagnosed with Gleason Score (GS) 7 PCa, as compared with low volume GS 6. This study confirms previous findings in a larger cohort of subjects that these "field effect" biomarkers can be useful for detecting cancer adjacent to histologically negative biopsies and may be indicative of occult aggressive PCa.
- The multi-gene ConfirmMDx™ for Prostate Cancer test demonstrated that epigenetic profiling is a significant predictor for PCa risk, especially to identify those men who should (not) undergo a repeat biopsy following a negative initial biopsy. An integrated risk management approach that combines this epigenetic assay with other risk factors, most notably histopathologic features of the cancer-negative initial biopsy, resulted in an improved prediction for the presence of PCa with sensitivity and negative predictive values of respectively 74% and 91%.

### **About ConfirmMDx for Prostate Cancer**

Over 650,000 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 disease leads to a high rate of repeat biopsies with over 40% of men receiving at least one repeat biopsy, and many receiving a 3<sup>rd</sup> and 4<sup>th</sup> 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” resulting from oncogenic processes at the DNA level in cells adjacent to cancer foci. 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, helps rule in high risk patients who may require repeat biopsies and potential treatment.

### **About MDxHealth**

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. The company's first commercial product, the ConfirmMDx™ for Prostate Cancer test, has been shown to help distinguish patients who have a true-negative biopsy from those who may have occult cancer. 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 brain and lung cancers. The company is based in Irvine, California with a European headquarters in Liege, Belgium. For more information visit MDxHealth website at [www.mdxhealth.com](http://www.mdxhealth.com).

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