NEWS RELEASE **REGULATED INFORMATION**

MDxHealth ConfirmMDx Biomarker Associated with the Risk of Recurrence for Early Stage Prostate Cancer Patients

Validation Study Data Published in *The Journal of Urology®*

IRVINE, California, and HERSTAL, BELGIUM – August 18, 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 one of the ConfirmMDx® for Prostate Cancer epigenetic genes is independently associated with risk of recurrence in patients with early prostate cancer (PCa). The results from this study, published in *The Journal of Urology®* *[The Journal of Urology (2014), doi: 10.1016/j.juro.2014.04.082],* suggest that epigenetic analysis could play a clinical role in identifying patients who have a slow growing cancer eligible for active surveillance from those with a higher risk of recurrence who may benefit from a more aggressive therapeutic approach.

One of the most significant challenges in diagnosing early stage PCa is proper staging and grading of the patients in order to choose the best treatment plan. Current methods such as clinical staging, PSA serum level and biopsy tissue Gleason score are helpful, but have limited prognostic value. Therefore, more accurate and objective prediction of PCa disease recurrence is very important. . The gene glutathione *S*-transferase Pi 1 (*GSTP1*) is one of the three genes in the ConfirmMDx test and previous studies have indicated that this gene has been associated with different stages of PCa.

“The results of this independent validation study confirm previous data presented at the 2014 ASCO GU Cancer Symposium demonstrating the prognostic value of our ConfirmMDx genes,” stated Prof. Dr. Wim van Criekinge, Chief Scientific Officer of MDxHealth. “Furthermore, they illustrate the clinical importance of using epigenetic biomarkers, like *GSTP1*, to not only identify patients with prostate cancer but also inform the treating urologist about the aggressiveness of the disease for treatment decision making.”

The study, conducted by researchers from Johns Hopkins University Medical Center, evaluated the prognostic value of nine epigenetic genes using tissue from 452 patients (259 cases, 193 controls) presenting with biochemical recurrence, clinical recurrence, systemic metastases, or who died of their prostate cancer in a nested case-control study of patients surgically treated for clinically localized PCa. Out of the nine genes, the data showed that higher *GSTP1* methylation was the only one significantly associated with an increased risk of recurrence, especially for men with early stage PCa.

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 undetected 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 leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment. The company's tests are based on proprietary gene methylation (epigenetics) technology 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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