

MDxHealth Epigenetic Biomarkers Identify Men at Increased Risk of Prostate Cancer Recurrence

Data presented at EAU 2017 shows potential to improve personalized treatment

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CET, March 27, 2017 – MDxHealth SA (Euronext: MDXH.BR) today announced that results from a prospective study demonstrate that biomarkers from its ConfirmMDx® for Prostate Cancer test could help urologists monitor therapy response to improve the personalized treatment of castration resistant prostate cancer (CRPC).¹ CRPC is an aggressive form of the disease that doesn't respond to traditional, hormone deprivation therapies. The study findings were presented at the 2017 European Association of Urology (EAU) Annual Congress in London, England.

Researchers from Radboud University Medical Center and Ghent University found that men with CRPC (n=47) had higher concentrations of plasma cell-free DNA (cfDNA - fragments floating outside of cells in the bloodstream), and higher levels of methylation of the biomarkers detected by the ConfirmMDx for Prostate Cancer test, versus a control group (n=30) of healthy people.¹ DNA methylation, used by cells to control gene expression and hypermethylation of specific genes, is a hallmark of many cancers and has been shown to predict cancer progression.

“The prognosis for men with CRPC is poor, with median survival times ranging from 9 to 22 months,” **said Prof. Dr. Jack Schalken, study investigator and Research Director, Radboud University Medical Center, Department of Urology, Nijmegen, The Netherlands.** “The identification of reliable biomarkers for CRPC will ultimately help urologists to more effectively stratify patients in this population to receive the treatment that will provide the greatest potential for extending life.”

In this study, the median levels of cfDNA of men with CRPC were significantly higher than in the age-matched controls and men <35 years of age ($p<0.01$).¹ Hypermethylation of GSTP1 was observed in 91% of men with CRPC at baseline, prior to treatment initiation, and significantly higher than in both male control groups ($p<0.02$).¹ Methylated APC was also higher in men with CRPC at baseline versus the control group ($p<0.01$).¹ Patients were stratified into four groups to assess overall survival according to cfDNA concentration at baseline and GSTP1/APC response to treatment with chemotherapy, abiraterone or enzalutamide. The group with both samples below the median had significantly less prostate cancer-related deaths ($p<0.02$).¹

“MDxHealth's research collaborations help us to discover new applications for biomarkers to expand our portfolio of molecular diagnostics for uro-oncology,” **said Dr. Jan Groen, CEO of MDxHealth.** “This study is another strategic milestone in our ongoing development of liquid biopsy products to help urologists detect prostate cancer recurrence and assess treatment response.”

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 Twitter at: twitter.com/mdxhealth.

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References:

1. Hendriks R, et al. (2017) Cell free DNA methylation markers as predictors of treatment response and prognosis for castration-resistant prostate cancer. European Association of Urology (EAU) Annual Meeting. Abstract #490. 26 March 2017.

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