NEWS RELEASE

MDxHealth Announces Positive Data from Pan-European Clinical Validation Study of SelectMDx

SelectMDx demonstrates accurate identification of both low-risk and aggressive prostate cancer across all patient groups

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CET, March 18, 2019 – MDxHealth SA (Euronext: MDXH.BR) today announces that positive data from a pre-biopsy clinical validation and optimization study of SelectMDx® were presented at the 34th Annual European Association of Urology (EAU) conference in Barcelona, Spain, March 15-19 2019.

This pan-European multicenter clinical study was designed to optimize and validate SelectMDx in assessing the risk of high-grade prostate cancer (PCa) in men with elevated prostate specific antigen levels (PSA). Data from the study showed that SelectMDx accurately predicts both low-risk as well as aggressive prostate cancer across all patient groups.

"This retrospective clinical validation study clearly confirms the value of the test to guide urologists to identify men at risk for aggressive disease, who may benefit from a biopsy or mpMRi procedure," **said Dr. Jack Schalken, Professor of Experimental Urology at the Radboud Medical Center in Nijmegen, The Netherlands**. "The performance of SelectMDx in this multicenter study confirms previous published data for the intended use of the test."

Study Design and Results

The study population consisted of 1,955 men from The Netherlands, France and Germany with suspected prostate cancer and who underwent initial prostate biopsies between December 2007 and December 2014.

Subjects were divided into training and validation cohorts. Post-DRE urine samples were collected from all subjects prior to biopsy and were evaluated with SelectMDx. The urinary RNA biomarkers were combined with other risk factors in a clinical model, and model coefficients were optimized for maximum sensitivity and negative predictive value (NPV) for ≧ GG2 PCa in training cohort subjects with PSA <10 ng/mL. Version 2.0 of the Prostate Cancer Prevention Trial (PCPT) Risk Calculator was used for comparison.

For validation cohort subjects with PSA <10ng/mL (N=715), SelectMDx AUC was 0.82, sensitivity 89%, specificity 53% and NPV 95%, whereas the PCPTRC AUC was 0.70. SelectMDx performance for the full validation cohort (all PSA levels, N=916) was AUC 0.85, with sensitivity and NPV of 93% and 95%, respectively.

"These data provide further evidence of SelectMDx's ability to provide actionable results, which can help urologists making important clinical decisions," **said Mike McGarrity, Chief Executive Officer of MDxHealth.** "In addition, we believe that routine implementation of SelectMDx could lead to substantial cost savings for healthcare systems and benefit patients by reducing the number of unnecessary invasive diagnostic procedures and treatments."

In France, Germany and The Netherlands combined, about 400,000 prostate biopsies are performed annually, resulting in about 115,000 newly diagnosed PCa patients per year. A recent cost-effectiveness study for SelectMDx in these countries where SelectMDx is used to stratify men for biopsy based on the probability of them harboring the aggressive form of PCa, showed cost savings per patient per year of $1,402 in France, $505 in Germany and $147 in the Netherlands.

On an annual basis the overall savings for the healthcare systems in these countries were respectively $184 million, $68 million and $3 million. In March 2018, SelectMDx was included in the EAU clinical guidelines, which assist clinicians in making informed treatment decisions. Since the introduction of SelectMDx in Europe in 2016, over 19,000 patients have been tested with SelectMDx.

About SelectMDx® for Prostate Cancer

Of the nearly 2 million prostate biopsies performed each year, less than a third identify cancer. Most of these men could have avoided a painful and invasive prostate biopsy procedure, with its associated complications and costs. SelectMDx for Prostate Cancer is a proprietary urine-based, molecular diagnostic test that offers a non-invasive liquid biopsy method to assess a patient's risk for prostate cancer. SelectMDx helps identify men at increased risk of harboring aggressive, potentially lethal, prostate cancer who may benefit most from a prostate biopsy and earlier detection. The test delivers a negative predictive value (NPV) of 98% for clinically significant disease, helping to reduce the need for MRI procedures and invasive prostate biopsies by up to 50%, thereby reducing healthcare costs. The test has been included in the 2018 European Association of Urology (EAU) clinical guidelines.

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 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 social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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