



MDxHealth Completes Enrollment of Second ConfirmMDx Clinical Utility Study

PASCUAL Study Expected to Support Expanded Reimbursement

IRVINE, CA, and HERSTAL, BELGIUM – April 20, 2015 – MDxHealth SA (Euronext: MDXH.BR) today announced that it has completed patient enrollment into its prospective, randomized PASCUAL clinical utility study with ConfirmMDx® for Prostate Cancer. The study, which will evaluate the impact of the ConfirmMDx test results on physician decisions for repeat biopsy, enrolled 600 patients from 17 leading urology practices across the U.S.

"We are pleased with the rapid enrollment of patients into the PASCUAL study, which illustrates the need for a novel biomarker like ConfirmMDx to assist with clinician-patient decisions concerning a repeat prostate biopsy," stated principal investigator Neal Shore, M.D. Medical Director, Carolina Urologic Research Center, Atlantic Urology Clinics, Myrtle Beach, South Carolina. "Completing enrollment of the study ahead of schedule is an early indication of the importance of this test for urologists and their patients."

"Medicare coverage for ConfirmMDx for Prostate Cancer is a significant achievement for the company and we are committed to taking all the steps necessary to ensure continued and expanded availability to men suspected of harboring prostate cancer," noted Dr. Jan Groen, CEO of MDxHealth. "In today's value-based healthcare environment, well-designed clinical utility studies are required to demonstrate improved patient outcomes and gain insurance coverage, which in the end provides patients with access to these important tests."

The ConfirmMDx for Prostate Cancer test, which helps urologists identify low risk men who may forego unnecessary repeat biopsy procedures, qualified for Medicare coverage on November 3, 2014. MDxHealth is conducting the PASCUAL study and enrolling providers into its Certification and Training Registry as part of an ongoing commitment to ensure appropriate use of the ConfirmMDx test, in line with the LCD providing coverage of the test. If the interim analysis demonstrates a substantially lower repeat biopsy rate, Palmetto GBA will expand physician participation in the ConfirmMDx Registry, effectively increasing the number of Medicare patients covered. Unrestricted Medicare coverage, with the Registry requirement removed, is expected upon publication of favorable PASCUAL study results when the study is concluded.

About ConfirmMDx® for Prostate Cancer

Up to 1 million 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 sample less than 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 epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) 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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