NEWS RELEASE

MDxHealth's ConfirmMDx for Prostate Cancer Test Qualifies for Medicare Coverage Effective November 3, 2014

Company initiates enrollment into prospective PASCUAL clinical utility trial

IRVINE, California, and HERSTAL, BELGIUM – September 23, 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 its ConfirmMDx® for Prostate Cancer test qualifies for Medicare coverage effective November 3, 2014.

The Centers for Medicare and Medicaid Services (CMS) released the final version of the coverage policy issued by Palmetto GBA, the Medicare administrator responsible for the MolDx technology assessment program that evaluated the ConfirmMDx test:

MolDX Title: ConfirmMDx Epigenetic Molecular Assay
LCD#: L35368

As part of an ongoing commitment to ensure that Medicare covers the appropriate use of the ConfirmMDx test, Palmetto GBA expects MDxHealth to continue accruing patients in the prospective, randomized PASCUAL clinical utility trial currently in process, and to enroll providers into it's Certification and Training Registry. The LCD provides for coverage initially limited to patients of physicians enrolled in the ConfirmMDx Registry. MDxHealth will conduct an interim analysis of the PASCUAL study to determine the repeat biopsy rate, and expects to complete the interim analysis in 2015. Provided the interim analysis yields positive results showing a substantially lower repeat biopsy rate, Palmetto will expand physician participation in the ConfirmMDx Registry, effectively increasing the number of Medicare patients covered. If the interim analysis demonstrates poor accrual, or fails to demonstrate a substantially decreased repeat biopsy rate, the LCD indicates that limited coverage will continue until either 1,200 patients have been tested or 3 years from the effective date of the LCD, which ever occurs first. MDxHealth expects to have tested 1,200 patients within the PASCUAL trial and the Registry by Q2 2016. Unrestricted Medicare coverage, with the Registry requirement removed, is expected with favorable PASCUAL trial findings.

"The ConfirmMDx for Prostate Cancer test is an important tool validated to aid urologists with management of patients suspected to harbor undetected prostate cancer and the need for a repeat biopsy. The PASCUAL clinical trial is an opportunity to prospectively demonstrate how urologists utilize the test results in a patient population with a previous negative biopsy result," said principal study investigator Neal Shore, M.D. Medical Director, Carolina Urologic Research Center Partner, Atlantic Urology Clinics, Myrtle Beach, South Carolina. "Prostate cancer is one of the most common cancers in U.S., with 1 in 6 men diagnosed during their lifetime. Prostate cancer can be most effectively treated if caught early, so ConfirmMDx serves a vital role. The ConfirmMDx test provides valuable genomic insights beyond standard pathology review, helping urologists make informed decisions about the need for repeat biopsy on high risk patients."

"We are pleased to announce this important milestone for the ConfirmMDx test, and MDxHealth. The decision by Palmetto GBA's MolDX technology assessment program to cover ConfirmMDx for Medicare beneficiaries under the conditions set forth in the LCD establishes ConfirmMDx as a "reasonable and necessary" test for the management of men suspected to have occult cancer. Medicare's decision will facilitate negotiations with private insurance companies as well," stated Dr. Jan Groen, CEO of MDxHealth. "Initial patient enrollment in the PASCUAL trial has been robust and we are confident this study will yield positive results corresponding to those already reported in the clinical utility study we published earlier this year."

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 occult 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 45 studies on over 5,000 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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