MDxHealth Announces Approval for SelectMDx for Prostate Cancer by New York State

IRVINE, CA, and HERSTAL, BELGIUM – 07.00 CET, 26 November 2018 – MDxHealth SA (Euronext: MDXH.BR) today announces that the New York State Department of Health has approved its SelectMDx test for Prostate Cancer. This completes MDxHealth's state licensing requirements for SelectMDx, allowing the Company to offer the liquid biopsy test in all 50 states across the US.

SelectMDx is a proprietary, non-invasive urine-based molecular diagnostic test to identify men at increased risk of harboring aggressive prostate cancer, who may benefit most from earlier detection. Studies have shown that the test can reduce the need for unnecessary invasive biopsies and MRI procedures by up to 50%. A prospective clinical utility study recently published in the journal Urology Practice clearly demonstrated the value of SelectMDx in guiding urologists with their initial prostate biopsy decision-making. Similarly, a US based study published in the Journal of Urology assessing the cost-effectiveness of SelectMDx projected potential annual healthcare cost savings of over $500 million.

"We’re thrilled to receive this approval from New York State which means SelectMDx will now be widely available to all physicians and their patients throughout the United States," said Dr. Jan Groen, MDxHealth’s CEO. "This is a major milestone for our SelectMDx reimbursement and commercial strategy. It will support the growth of our test volumes for SelectMDx in the US, an important market, as well as in other territories."

The New York State Department of Health’s Clinical Laboratory Evaluation Program (CLEP) regulates and oversees clinical diagnostic laboratories that test specimens from New York State residents, including Laboratory Developed Tests (LDTs). The CLEP seeks to ensure the accuracy and reliability of test results in clinical laboratories located in, or accepting specimens from, New York State residents. It is widely regarded as one of the most rigorous review processes due to its stringent quality standards.

The MDxHealth laboratory has been accredited by the College of American Pathologists (CAP) since 2012, and the Centers for Medicare and Medicaid Services (CLIA) since 2011. In addition, the laboratory is licensed by the California Department of Public Health, Pennsylvania State Department of Health, State of Rhode Island Department of Health and Maryland Department of Health.

About SelectMDx® for Prostate Cancer

SelectMDx for Prostate Cancer is a proprietary, urine-based molecular diagnostic test that offers a non-invasive 'liquid biopsy' method to assess a man’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 helps to reduce the need for MRI procedures and invasive prostate biopsies by up to 50%, thereby improving quality of life and lowering healthcare costs per patient. SelectMDx is available in the US and all EU member states. Since the introduction of the SelectMDx test in mid-2016, over 23,000 patients have been tested and 15 commercial contracts have been signed with US based insurance companies. 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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