

MDxHealth Provides Business Update

IRVINE, CA, and HERSTAL, BELGIUM – November 29, 2022 – MDxHealth SA (NASDAQ/Euronext: MDXH), a commercial-stage precision diagnostics company, today provided clinical and reimbursement product developments, updated guidance for 2022, and initial guidance for 2023.

Select mdx reimbursement update

Under the foundational LCD (Local Coverage Decision) process recently implemented by the Molecular Diagnostics Services (MoIDX) Program administered by Palmetto GBA, all tests within an LCD-covered indication must submit a Technical Assessment (TA) for review and consideration. The indication for use of Select mdx is covered by Medicare's foundational LCD [Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer](#), which became effective in July 2022. The Select mdx TA has already been submitted and we are engaged in an interactive review process with MoIDX. Based on our most recent communication with MoIDX, a final coverage decision is not expected until H1 2023.

NCCN Guidelines expand Genomic Prostate Score (GPS) indication to include high-risk patients

The recently released [NCCN for Prostate Cancer Guideline \(Version 1.2023\)](#)* expands the indication for use of the GPS test to include high-risk patients with localized prostate cancer. In August 2022, mdxhealth announced that it acquired the Oncotype DX Genomic Prostate Score® (GPS) test from Exact Sciences, further solidifying the Company's leadership in the precision diagnostics urology market. This expanded criteria to address high-risk patients provides additional validation for the clinical utility of GPS in making prostate cancer treatment decisions and enables us to more fully serve our targeted patient population.

Michael K. McGarrity, CEO of mdxhealth, commented: "Securing Medicare reimbursement for new molecular diagnostic technologies is now a more rigorous and iterative process under the new Foundational LCD program. Due to the additional time required to obtain Medicare coverage, the Company no longer expects to receive Medicare payments for Select mdx tests in 2022. Based on this development, coupled with revenue cycle timing associated with the acquisition and integration of the GPS test, the Company is revising its 2022 revenue guidance to \$36.5-37.5 million from \$40-42 million. We remain confident in our ability to address any remaining questions with MoIDX, which we believe will lead to a positive reimbursement decision for Select mdx in the first half of 2023. To further underscore the growing diagnostic value of Select mdx, we are also pleased to report that the results of an independent, multi-institutional clinical study was recently recognized as a best poster by the American Urological Association, demonstrating the diagnostic accuracy of Select mdx and as well as its complementary utility with mpMRI for the prediction of prostate cancer in biopsies.

"Further, we are also pleased to note the expanded indication for our GPS test in the recently updated NCCN Prostate Cancer guidelines", **continued Mr. McGarrity.** "The addition of GPS to our current menu of tests targeted into urology and prostate cancer reflects our strategy to generate sustainable growth and enable mdxhealth to become the leading precision diagnostics company with the most comprehensive test menu focused on prostate cancer. While early, we are well into our integration plan for our GPS test and have our expanded field sales organization in place to support continued growth. With multiple levers for sustainable revenue growth, the company is initiating 2023 revenue guidance of \$65-70 million."

About mdxhealth®

MDxhealth is a commercial-stage precision diagnostics 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 and prognosis of recurrence risk. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and U.S. headquarters and laboratory operations based in Irvine,

California, with additional laboratory operations in Plano, Texas. 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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This press release contains forward-looking statements and estimates with respect to the anticipated future performance of MDxHealth and the market in which it operates, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "potential," "expect," "will," "goal," "next," "potential," "aim," "explore," "forward," "future," and "believes" as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements regarding the acquisition of Oncotype DX® GPS prostate cancer business from Exact Sciences including statements regarding the anticipated benefits of the acquisition; statements. Such statements and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable but may not prove to be correct. Actual events are difficult to predict, may depend upon factors that are beyond the company's control, and may turn out to be materially different. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, product development efforts, our strategies, positioning, resources, capabilities and expectations for future events or performance. Important factors that could cause actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations, and the demand for our products; our ability to successfully and profitably market our products; the acceptance of our products and services by healthcare providers; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; the possibility that the anticipated benefits from our business acquisitions like our acquisition of the Oncotype DX® GPS prostate cancer business will not be realized in full or at all or may take longer to realize than expected; and the amount and nature of competition for our products and services. Other important risks and uncertainties are described in the Risk Factors sections of our most recent Annual Report on Form 20-F and in our other reports filed with the Securities and Exchange Commission. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this release to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based unless required by law or regulation. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of MDxHealth in any jurisdiction. No securities of MDxHealth may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. securities laws.

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**[NCCN Prostate Cancer Guidelines 1.2023 Discussion Update in Progress \(Nov.29, 2022\)](#)*