

Lucid Diagnostics Launches Next-Generation EsoGuard® Esophageal DNA Test and Announces Upcoming Investor Day

EsoGuard 2.0 incorporates advanced molecular techniques and leverages improvements in sample DNA yields and processes to enhance assay performance and lower costs

Lucid Diagnostics Investor Day, where Lucid executives, key opinion leaders, and other experts will discuss Lucid's business and technologies, to be held in New York City on December 13th

NEW YORK, Nov. 9, 2023 /PRNewswire/ -- **Lucid Diagnostics Inc.** (Nasdaq: LUCD) ("Lucid" or the "Company") a commercial-stage, cancer prevention medical diagnostics company, and majority-owned subsidiary of PAVmed Inc. (Nasdaq: PAVM, PAVMZ) ("PAVmed"), today announced that its CAP-accredited, CLIA-certified laboratory, LucidDx Labs, Inc., has launched the next generation of the [EsoGuard® Esophageal DNA test](#) ("EsoGuard 2.0") for the detection of esophageal precancer, having demonstrated enhanced assay performance and lower costs in extensive validation studies. All commercial and research samples received by the laboratory will now be processed using the EsoGuard 2.0 assay. Lucid also announced that it will be hosting an Investor Day on December 13, 2023, in New York City.

"The launch of EsoGuard 2.0 is a seminal milestone for our company and the culmination of over a year of meticulous R&D work by our Chief Scientific Officer, [Suman Verma, M.D., Ph.D.](#), and her dedicated and talented team," said [Lishan Aklog, M.D.](#), Lucid's Chairman & Chief Executive Officer. "EsoGuard had previously demonstrated unprecedented cancer and precancer detection results, including detecting 100 percent of esophageal cancers and over 80 percent of precancers in a recent study from the National Cancer Institute-funded BETRNet consortium. EsoGuard 2.0 improves upon EsoGuard 1.0's already outstanding performance in multiple respects, including by enhancing DNA yield, streamlining down-stream processes that incorporate advanced molecular techniques and more efficient bioinformatics, and enabling higher-throughput testing. These improvements also lower the per-sample costs of the assay, which we expect to decrease even further in the coming months when we upgrade our NGS-sequencing platform to a higher-throughput model to accommodate increased EsoGuard testing volume. We appreciate the critical input of Sandy Markowitz, M.D., Ph.D., and his colleagues at Case Western Reserve University, the inventors of EsoGuard, in helping us reach this milestone."

The results of the analytical validation studies of the EsoGuard assay, culminating in EsoGuard 2.0, have been accepted for presentation at the upcoming Association of Molecular Pathology Annual Meeting (AMP 2023) on November 18th.

The EsoGuard assay involves first extracting DNA from esophageal cells collected by the EsoCheck® Cell Collection Device. The DNA then undergoes bisulfite conversion, which tags sites which are not methylated. Two genes, VIM and CCNA1, with 31 methylation sites that correlate with esophageal precancer and cancer, are amplified using polymerase chain reaction ("PCR") techniques and then sequenced using next-generation sequencing ("NGS") techniques. Advanced bioinformatics software analyzes the DNA sequence data and determines the proportion of the 31 target sites which are methylated, returning a positive or negative EsoGuard result. The original version of the assay used a singleplex technique, which required the DNA to be split and separately processed for each gene. EsoGuard 2.0 uses multiplexing which allows both genes to be interrogated on a single DNA sample. This breakthrough allows the laboratory to run the assay three times and call positive and negative results by consensus, blunting stochastic noise for low positive samples near the cutoff. The next-generation assay underwent rigorous analytical and clinical validation studies, including head-to-head comparisons of multiplexed triplicate consensus versus singleplex techniques, consistent with CLIA standards. Clinical validation analysis included samples from the ESGUARD-BE-1 study and demonstrated improved sensitivity and specificity.

Lucid will host an Investor Day event to be held in New York, NY on December 13, 2023. The Lucid executive leadership team will present on several topics including the company's commercial progress, the launch of EsoGuard 2.0, and the recent expansion of clinical utility and clinical validity data to support adoption and reimbursement. Key opinion leaders in the field of esophageal disease and other experts will present on their experiences with EsoGuard and its impact on patient outcomes. Details on how to register for the Investor Day

will be made available on the Investor Relations section of the Company's website.

About Lucid Diagnostics

Lucid Diagnostics Inc. is a commercial-stage, cancer prevention medical diagnostics company, and subsidiary of PAVmed Inc. (Nasdaq: PAVM). Lucid is focused on the millions of patients with gastroesophageal reflux disease (GERD), also known as chronic heartburn, who are at risk of developing esophageal precancer and cancer.

Lucid's [EsoGuard® Esophageal DNA Test](#) is performed on samples collected in a brief, noninvasive office procedure with its EsoCheck® Esophageal Cell Collection Device. EsoCheck and EsoGuard are the first and only commercially available tools designed with the goal of preventing cancer and cancer deaths through widespread, early detection of esophageal precancer in at-risk patients.

For more information, please visit www.luciddx.com and for more information about its parent company PAVmed, please visit www.pavmed.com.

Forward-Looking Statements

This press release includes forward-looking statements that involve risk and uncertainties. Forward-looking statements are any statements that are not historical facts. Such forward-looking statements, which are based upon the current beliefs and expectations of Lucid's management, are subject to risks and uncertainties, which could cause actual results to differ from the forward-looking statements. Risks and uncertainties that may cause such differences include, among other things, volatility in the price of Lucid's common stock; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance Lucid's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from Lucid's clinical and preclinical studies; whether and when Lucid's products are cleared by regulatory authorities; market acceptance of Lucid's products once cleared and commercialized; Lucid's ability to raise additional funding as needed; and other competitive developments. In addition, Lucid continues to monitor the COVID-19 pandemic and the pandemic's impact on Lucid's businesses. These factors are difficult or impossible to predict accurately and many of them are beyond Lucid's control. In addition, new risks and uncertainties may arise from time to time and are difficult to predict. For a further list and description of these and other important risks and uncertainties that may affect Lucid's future operations, see Part I, Item 1A, "Risk Factors," in Lucid's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as the same may be updated in Part II, Item 1A, "Risk Factors" in any Quarterly Report on Form 10-Q filed by Lucid Diagnostics after its most recent Annual Report. Lucid disclaims any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in its expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

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