

Lucid Diagnostics Announces PREVENT and PREVENT-FF Registries of EsoGuard® Esophageal Precancer Detection

Clinical registries are collecting real-world clinical utility and clinical validity data on EsoGuard testing in general at-risk populations and firefighters, respectively

Initial combined analysis of clinical utility in 437 patients documents excellent concordance of EsoGuard results with subsequent medical decision-making and over 99 percent technical success

NEW YORK, Oct. 31, 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 two longitudinal clinical registries which are collecting real-world clinical utility and clinical validity data on [EsoGuard® Esophageal DNA testing](#) for the detection of esophageal precancer. The **P**rospective **R**EVUE of **E**sophageal Precancer Detection in **A**T-Risk Patients (PREVENT) Registry collects data on EsoGuard testing in the general at-risk population, while the PREVENT-FF Registry focuses exclusively on at-risk firefighters. The Company released positive clinical utility data from an initial combined analysis of patients from both registries.

The PREVENT Registry prospectively enrolls patients with well-established esophageal precancer risk-factors referred by a physician to Lucid for EsoGuard testing. Lucid clinical personnel perform esophageal cell collection using the EsoCheck® Cell Collection Device and Lucid's CLIA-certified laboratory then performs the EsoGuard test on the sample. Subsequent management, including referral for upper endoscopy, is dictated exclusively by the referring physician. The PREVENT-FF Registry prospectively enrolls firefighters with additional esophageal precancer risk factors referred for EsoGuard testing who participate in one of Lucid's #CheckYourFoodTube Precancer Testing Events. A total of 624 patients have been enrolled in the two registries to date.

"PREVENT and PREVENT-FF are key pillars of our commercial strategy for EsoGuard and we are excited to see the initial fruits of our investment in these real-world clinical registries," said [Lishan Aklog, M.D.](#), Lucid's Chairman & Chief Executive Officer. "The initial combined analysis will supplement our growing clinical utility evidence base, including the previously announced CLUE and San Antonio Firefighter studies. The PREVENT and PREVENT-FF registries, however, are designed to generate a much broader data set than these clinical utility studies. The registries are open-ended, and our goal is to enroll a substantial proportion of all patients undergoing EsoGuard testing by Lucid personnel at Lucid Test Centers, including satellite testing at physician offices, and health fairs, including at fire departments. They also penetrate much further into the patient journey than the previously reported studies by going beyond the initial medical decision-making. The registries have a meaningful longitudinal follow-up period and include confirmatory endoscopy findings in those with positive EsoGuard results. As a result, they will provide both clinical utility and clinical validity data to further support our ongoing commercial and market access efforts, including our critical, expanding engagement with commercial payors. The full data set will also feed our active research and development program on the EsoGuard assay and a pipeline of potential future commercial products. Finally, the PREVENT-FF registry is a testament to our deep commitment to provide access to early precancer detection to reduce the tragic toll that cancer inflicts on firefighters who sacrifice so much for us."

A manuscript on the initial analysis combining clinical utility data from both registries, entitled [Real World Experience and Clinical Utility of EsoGuard® - Interim Data from the Lucid Registry](#), was recently posted on the leading health sciences preprint server, medRxiv, and has been submitted for peer-reviewed publication. Of the 517 patients enrolled at the date of this manuscript, over 304 were firefighters and 437 had complete clinical utility data. EsoCheck cell collection was technically successful in 99.6 percent and sufficient DNA was collected in over 95 percent, replicating near-perfect technical success rates and high DNA yields previously reported by Lucid. The mean cell collection time was less than two minutes, besting prior reports. The prescribing physician referred all 55 patients with positive EsoGuard results (14 percent) for confirmatory endoscopy. 352 of the 354 patients with negative EsoGuard results were not referred for endoscopy. This represents 100 percent concordance between a positive EsoGuard test result and subsequent physician medical decision-making, and a 99.4 percent concordance with a negative result, consistent with professional society guidelines. These outstanding clinical utility results align with the previously announced CLUE and San Antonio Firefighter studies. They again demonstrate that EsoGuard allows physicians to appropriately triage at-risk patients to confirmatory

endoscopy in a manner broadly consistent with established, and recently updated, professional society guidelines, in this case, eliminating the need for over 350 costly, invasive, and inconvenient endoscopies.

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. EsoGuard and EsoCheck 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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