Lucid Diagnostics Announces Positive Data from the First Prospective Clinical Validation Study of EsoGuard® Esophageal Precancer Testing in a Screening Population

Prospective VA screening study demonstrates excellent EsoGuard sensitivity of 92.9% and negative predictive value of 98.6% compared to upper gastrointestinal endoscopy

Authors conclude that EsoGuard is a "powerful screening tool" for esophageal precancer and cancer

NEW YORK, March 21, 2024 /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 investigators at the Louis Stokes Cleveland Veterans Affairs Medical Center, led by Katarina B. Greer, M.D.,M.S., Associate Professor of Medicine at Case Western Reserve University School of Medicine, have released data from a Department of Defense funded prospective clinical validation study of patients who met strict national society guideline criteria for esophageal precancer testing. The study demonstrated excellent performance of Lucid's EsoGuard® Esophageal DNA test for esophageal precancer detection and is the first to present such clinical validity data in a screening population. The manuscript entitled *Non-endoscopic screening for Barrett's esophagus and Esophageal Adenocarcinoma in at risk Veterans* is available on the leading health sciences preprint server, medRxiv, pending peer review and publication.

"We are grateful to Dr. Greer and her co-investigators for this sentinel contribution to the clinical evidence supporting EsoGuard esophageal precancer testing," said Victoria T. Lee, M.D., Lucid's Chief Medical Officer. "Data from this clinical validation study, the first in an 'intended use' screening population, closely mirror EsoGuard performance data from two previously reported NCI-funded case-control clinical validation studies—the original multi-center study which first introduced the technology, and the recently completed BETRNet study whose results were posted as a preprint last year pending peer review and publication. Collectively, these three clinical validity studies demonstrate excellent EsoGuard sensitivity and negative predictive value, including unprecedented performance of a molecular diagnostic test in detecting a precancer. They strongly support EsoGuard's use as a widespread screening tool to prevent esophageal cancer through the early detection of esophageal precancer."

Dr. Lee added, "as previously reported, three published clinical utility studies have already documented near-perfect concordance between EsoGuard results and physician referral for upper gastrointestinal endoscopy. Physicians consistently utilized EsoGuard results to appropriately triage at-risk patients resulting in more cost-effective utilization of endoscopy for esophageal precancer detection. The clinical validity and clinical utility data, coupled with multiple national society guidelines and consensus statements supporting EsoGuard esophageal precancer detection, provides a strong foundation of critical evidence needed to support broad EsoGuard medical policy coverage and a line of sight to CMS coverage, in particular."

The manuscript reports on 128 eligible patients with no prior history of upper gastrointestinal endoscopy (EGD) who met criteria for esophageal precancer screening based on current American College of Gastroenterology guidelines (presence of chronic heartburn and at least three of six additional risk factors—age over 50 years, male sex, white race, obesity, smoking and positive family history). 124 patients underwent successful non-endoscopic esophageal cell sampling using the EsoCheck® Cell Collection Device followed by EGD. Biopsies were performed during EGD if esophageal precancer was suspected based on appearance. Twelve patients with esophageal precancer and two patients with esophageal cancer were confirmed on endoscopy for an overall disease prevalence of 12.9%. 111 patients had sufficient DNA for EsoGuard analysis. EsoGuard sensitivity and specificity were 92.9% and 72.2%, respectively. Negative and positive predictive were 98.6% and 32.5% respectively. Although specificity was somewhat lower than in prior studies—likely due to the absence of routine biopsies of the gastroesophageal junction, absence of biopsies in patients with minimal or no suspicious areas on EGD, a higher mean age, and higher proportion of current smokers—a solid positive predictive value was preserved, resulting in a 2.5-fold increase in the positive yield of EGD. Good tolerance and acceptability of EsoCheck cell sampling was also reported.

The authors conclude that *"[g]iven the increasing prevalence of [esophageal cancer]... and improved effectiveness of ablative and endoscopic resection techniques available to patients with early stages of disease, this screening platform [EsoGuard] opens the window to improved prognosis for [esophageal cancer] by increasing access to minimally invasive, well tolerated office-based testing."*

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, performed on samples collected in a brief, noninvasive office procedure with its EsoCheck® Esophageal Cell Collection Device - 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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