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PAVmed Subsidiary Lucid Diagnostics Receives CE Mark Certification for its EsoCheck® Esophageal Cell Collection Device

NEW YORK, May 26, 2021 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (“PAVmed”), a highly differentiated, multi-product, commercial-stage medical device company, and its major subsidiary Lucid Diagnostics Inc. (“Lucid”), today announced that Lucid’s EsoCheck® Esophageal Cell Collection Device with Collect+Protect™ technology (“EsoCheck”) has received CE Mark certification.

EU-based Notified Body TÜV Rhineland LGA Products GMBH issued a CE Certificate, effective May 24, 2021, declaring that EsoCheck conforms to the essential requirements of Medical Device Directive 93/42/EEC. With CE Mark secured, EsoCheck may now be marketed in CE Mark European countries, which include the European Economic Area (the EU, Norway, Iceland, and Lichtenstein), Switzerland, and, until July 1, 2023, the United Kingdom.

EsoCheck is an FDA-cleared swallowable balloon capsule catheter, which allows a clinician to sample surface cells from the esophagus in a less than 5-minute non-invasive office procedure, the only such device capable of doing so in an anatomically targeted fashion, without sample dilution or contamination ([EsoCheck animation](#)). EsoCheck, paired with Lucid’s EsoGuard® Esophageal DNA Test (“EsoGuard”), are the first and only commercially available diagnostic technologies capable of serving as a widespread screening tool to prevent deaths through the early detection of esophageal precancer and cancer in at-risk chronic heartburn patients. As a “General IVD” under Europe’s In-Vitro Diagnostic Medical Devices Directive 98/79/EC, EsoGuard only requires self-certification, which Lucid and its authorized representative expect to complete in the very near future.

“Chronic heartburn is as ubiquitous, and esophageal cancer as deadly, in Europe as it is in the U.S. so this certification represents yet another important milestone in our mission to prevent deaths through the early detection of esophageal precancer and cancer,” said Lishan Aklog, M.D., PAVmed’s Chairman and Chief Executive Officer, and Lucid’s Executive Chairman. “Lucid has already developed strong relationships with European key opinion leaders in esophageal disease who are participating in our pivotal clinical trials. We look forward to leveraging these relationships and proceeding with a commercial launch in select European countries in the near future.”

About PAVmed and Lucid

PAVmed Inc. is a highly differentiated, multi-product, commercial-stage medical technology company with a diversified product pipeline addressing unmet clinical needs encompassing

a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its major subsidiary, Lucid Diagnostics Inc., markets the first and only commercial tools for widespread early detection of esophageal precancer and cancer – the EsoGuard[®] Esophageal DNA Test and EsoCheck[®] Esophageal Cell Collection Device. Its GI Health division also includes the complementary EsoCure[™] Esophageal Ablation Device with CalduS[™] Technology. Its Minimally Invasive Interventions markets its CarpX[®] Minimally Invasive Device for Carpal Tunnel Syndrome. Other divisions include Infusion Therapy (PortIO[™] Implantable Intraosseous Vascular Access Device and NextFlo[™] Intravenous Infusion Set), and Emerging Innovations (non-invasive laser-based glucose monitoring, pediatric ear tubes, and mechanical circulatory support). For more information, please visit www.pavmed.com, follow us on [Twitter](#), connect with us on [LinkedIn](#), and watch our videos on [YouTube](#). For more information on our majority owned subsidiary, Lucid Diagnostics Inc., please visit www.luciddx.com, follow Lucid on [Twitter](#), and connect with Lucid on [LinkedIn](#). For detailed information on EsoGuard, please visit www.EsoGuard.com and follow us on [Twitter](#), [Facebook](#) and [Instagram](#).

Forward-Looking Statements

This press release includes forward-looking statements that involve risks and uncertainties. Forward-looking statements are statements that are not historical facts. Such forward-looking statements, based upon the current beliefs and expectations of PAVmed'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 PAVmed's common stock, Series W Warrants and Series Z Warrants; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required advance PAVmed's products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from PAVmed's preclinical studies; whether and when PAVmed's products are cleared by regulatory authorities; market acceptance of PAVmed's products once cleared and commercialized; our ability to raise additional funding and other competitive developments. PAVmed has not yet received clearance from the FDA or other regulatory body to market many of its products. The Company has been monitoring the COVID-19 pandemic and its impact on our business. The Company expects the significance of the COVID-19 pandemic, including the extent of its effect on the Company's financial and operational results, to be dictated by, among other things, the success of efforts to contain it and the impact of actions taken in response. New risks and uncertainties may arise from time to time and are difficult to predict. All of these factors are difficult or impossible to predict accurately and many of them are beyond PAVmed's control. For a further list and description of these and other important risks and uncertainties that may affect PAVmed's future operations, see Part I, Item IA, "Risk Factors," in PAVmed'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 PAVmed after its most recent Annual Report. PAVmed 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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