NEW YORK, June 11, 2020 (GLOBE NEWSWIRE) -- PAVmed Inc. (Nasdaq: PAVM, PAVMZ) (the “Company” or “PAVmed”), a highly differentiated, multiproduct medical device company, today announced that its majority owned subsidiary, Lucid Diagnostics Inc. (“Lucid”), received preliminary gapfill payment determination for its EsoGuard™ Esophageal DNA Test (“EsoGuard”).

On June 9, 2020, the U.S. Center for Medicare and Medicare Services (“CMS”) published its “CY 2020 - Clinical Laboratory Fee Schedule Test Codes Preliminary Determinations” listing preliminary gapfill payment recommendations for the current review cycle. Medicare Administrative Contractor (MAC) Palmetto GBA recommended EsoGuard CPT code 0114U payment of $1,938.01 in 38 states and $2,690 in 12 states (including Florida, New Jersey and Pennsylvania) and two U.S. territories.

This preliminary payment determination will be subject to public comments until August 10, 2020, after which the final MAC-specific gapfilled payment determination will be posted. CMS will accept reconsideration requests for 30 days before finalizing the payment amount, which will apply for the period January 1, 2021 through December 31, 2023.

About EsoGuard

The EsoGuard Esophageal DNA Test is commercially available in the United States as a Laboratory Developed Test (LDT) and is the first DNA test designed to facilitate the diagnosis of Barrett’s Esophagus (BE) and related precursors to highly lethal esophageal adenocarcinoma (EAC) in patients with chronic heart burn, also known as gastroesophageal reflux disease (GERD).

EsoGuard is performed on cells sampled from the lower esophagus in a five-minute noninvasive office-based procedure. Next-generation sequencing (NGS) of DNA extracted from these cells is used to determine the epigenetic methylation status of 31 sites on two genes (VIM and CCNA1). A positive or negative result is determined based on algorithmic assessment of the percentage of DNA molecules for which a proportion of methylated sites on either gene exceeds a certain threshold. A positive result has been correlated, with greater than 90% sensitivity and specificity, with the presence of non-dysplastic BE, dysplastic BE or EAC, in a clinical study of 408 patients published in Science Translational Medicine.

About PAVmed
PAVmed Inc. is a highly differentiated, multiproduct commercial stage medical device company employing a unique business model designed to advance innovative products to commercialization rapidly and with less capital than the typical medical device company. This proprietary model enables PAVmed to pursue an expanding pipeline strategy with a view to enhancing and accelerating value creation while seeking to further expand its pipeline through relationships with its network of clinician innovators at leading academic centers. PAVmed’s diversified product pipeline addresses unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its four operating divisions include GI Health (EsoGuard™ Esophageal DNA Test, EsoCheck™ Esophageal Cell Collection Device, and EsoCure™ Esophageal Ablation Device with Calidus™ Technology), Minimally Invasive Interventions (CarpX™ Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO™ Implantable Intraosseous Vascular Access Device and NextFlo™ Highly Accurate Infusion Platform Technology), and Emerging Innovations (non-invasive laser-based glucose monitoring, pediatric ear tubes, and mechanical circulatory support). For more information, please visit [www.pavmed.com](http://www.pavmed.com), follow us on [Twitter](https://twitter.com), connect with us on [LinkedIn](https://linkedin.com), and watch our videos on [YouTube](https://youtube.com). For more information on our majority owned subsidiary, Lucid Diagnostics Inc., please visit [www.luciddx.com](http://www.luciddx.com), follow Lucid on [Twitter](https://twitter.com), and connect with Lucid on [LinkedIn](https://linkedin.com).

**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 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 Reports 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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