



## **PAVmed Subsidiary Lucid Diagnostics Receives FDA 510(k) Clearance for EsoCheck™**

NEW YORK, Jun. 24, 2019 (GLOBE NEWSWIRE) -- **PAVmed Inc. (Nasdaq: PAVM, PAVMZ)** (the “Company” or “PAVmed”), a highly differentiated, multi-product medical device company, today announced that its majority owned subsidiary, Lucid Diagnostics Inc. (“Lucid”), has received 510(k) marketing clearance for its EsoCheck Cell Collection Device™ (“EsoCheck”) from the U.S. Food and Drug Administration (FDA).

“I have spent my career seeking to improve the care of patients with gastroesophageal reflux disease and Barrett’s Esophagus and to prevent deaths from esophageal cancer. I have actively participated in the development of key advances in this field and am particularly excited that EsoCheck is now available as an FDA-cleared tool in our armamentarium. EsoCheck’s unique ability to sample cells from a targeted area of the esophagus has the potential to save lives through the early detection of esophageal abnormalities,” said Nicholas J. Shaheen MD, MPH, Professor of Medicine and Epidemiology and Chief of the Division of Gastroenterology and Hepatology at the University of North Carolina School of Medicine, Director of American College of Gastroenterology (ACG) Institute for Clinical Research and Education.

EsoCheck is a non-invasive cell collection device that is designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. The patient swallows a vitamin pill-sized capsule containing a small inflatable balloon attached to a thin catheter. As the catheter is withdrawn, it swabs the target area for a sample of cells and protects that sample from contamination as the device is removed. The sampled cells can then be subjected to any commercially available diagnostic test. FDA determined that EsoCheck is substantially equivalent to legally marketed predicate devices for its indications for use, namely “the collection and retrieval of surface cells of the esophagus in the general population of adults, 22 years of age or older”.

“I am excited to report this major milestone for PAVmed and Lucid,” said Lishan Aklog, MD, PAVmed’s Chairman and CEO and Lucid’s Executive Chairman. “We are proud to have received FDA clearance for EsoCheck just over one year from the day we founded Lucid and licensed this groundbreaking technology from Case Western Reserve University. We look forward to offering EsoCheck to physicians and patients this summer and believe EsoCheck presents many advantages over existing sponge-on-a-string esophageal cell collection devices. These devices have a capsule which must be digested in the stomach before it can be used to sample cells, while EsoCheck can begin sampling immediately upon insertion. More importantly, EsoCheck’s Collect+Protect™ technology allows it to perform a targeted sample of the lower esophagus, while spherical sponge-on-a-string devices sample cells from the entire esophagus, throat and mouth which dilutes and contaminates the lower esophageal cells.”

### **About PAVmed**

PAVmed Inc. is a highly differentiated, multiproduct medical device company employing a unique business model designed to advance innovative products to commercialization much more rapidly and with significantly 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. PAVmed’s diversified pipeline of products address unmet clinical needs encompassing a broad spectrum of clinical areas with attractive regulatory pathways and market opportunities. Its five lead technologies provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous

conditions of the esophagus (EsoGuard™/EsoCheck™), vascular access (PortIO™), pediatric ear infections (DisappEAR™) and medical infusions (NextFlo™). The company is also developing innovative products in other areas, such as catheters and tissue ablation, while seeking to further expand its pipeline through engagements with clinician innovators and leading academic medical centers. For more information, please visit [www.pavmed.com](http://www.pavmed.com), follow us on [Twitter](#), connect with us on [LinkedIn](#), and watch our videos on [YouTube](#).

### **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 to 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 any of its products. 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 1A, "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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