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## **PAVmed and Case Western Reserve University Finalize Definitive Licensing Agreement for Groundbreaking EsoCheck Technology**

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**Terms:**

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*PAVmed subsidiary Lucid Diagnostics Inc. secures exclusive worldwide license for EsoCheck*

*Rapid, highly accurate, office-based test utilizes a novel, non-invasive cell-sampling device coupled with proprietary DNA biomarkers to detect Barrett's Esophagus, precursor to the most common and lethal form of esophageal cancer, caused by acid reflux*

*First commercial product projected to launch in the U.S. in the first quarter of 2019, eventually targeting up to 50 million at-risk patients*

NEW YORK--(BUSINESS WIRE <sup>(1)</sup>)--**PAVmed Inc. (Nasdaq:PAVM, PAVMZ)**, a highly differentiated, multi-product medical device company, today announced it has finalized a definitive licensing agreement with Case Western Reserve University to develop and commercialize its groundbreaking EsoCheck technology.

EsoCheck is a rapid office-based alternative to diagnostic endoscopy that combines a non-invasive cell sampling device with a DNA biomarker test. Together these have been shown to be highly accurate in detecting Barrett's Esophagus, the primary precursor to the most common and lethal form of esophageal cancer caused by Gastroesophageal Reflux Disease (GERD), commonly known as heart burn or acid reflux.

In a simple five-minute test, 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 As the catheter is withdrawn, it swabs the target area for a sample of cells and protects that sample from contamination as the device is removed.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 sample is then tested for a panel of methylated DNA biomarkers that have been shown to be highly accurate in detecting Barrett's Esophagus. These data were recently published in a seminal report on a multicenter human clinical study (Moinova, *et al. Science Translational Medicine* 2018 Jan 17;10(424)).

Pursuant to the licensing agreement, newly-formed PAVmed subsidiary Lucid Diagnostics Inc. now owns the exclusive worldwide right to develop and commercialize both the EsoCheck cell sampling device and the DNA biomarker test, as well as additional related intellectual property.

"EsoCheck is a revolutionary technology that we believe will save many lives through the early detection of pre-cancerous conditions of the esophagus including Barrett's Esophagus," said PAVmed Chairman and CEO Lishan Aklog, M.D. "We are proud to have been selected to be the exclusive commercial partner of Case Western Reserve University in this important endeavor. Based on the dramatic results of the recently published multicenter clinical study, we believe widespread EsoCheck screening has the potential to have as great an impact on esophageal cancer as widespread Pap screening has had in preventing cervical cancer, targeting an estimated immediately addressable domestic market of several billion dollars."

A large multicenter National Institutes of Health (NIH) study of EsoCheck is underway and actively enrolling patients at Case Western Reserve University Hospital and other leading academic medical centers including the Cleveland Clinic, Johns Hopkins, Mayo Clinic, Washington University St. Louis and the University of North Carolina.

"Our multicenter NIH study aims to establish the clinical evidence for EsoCheck's widespread use as a screening test to detect Barrett's Esophagus, eventually targeting the estimated 50 million Americans with and without heartburn who are at risk," said principal investigator and EsoCheck co-inventor Amitabh Chak, M.D., professor of medicine at Case Western Reserve University School of Medicine, gastroenterologist at UH Digestive Health Institute, director of the Advanced Technology & Innovation Center of Excellence at University Hospitals Division of Gastroenterology and editorial board chair of *Gastrointestinal Endoscopy*, the preeminent journal in the field.

"The EsoCheck device is already being manufactured for human use in clinical trials and the EsoCheck DNA biomarker test is already being performed at a reference laboratory, which expects to receive CLIA certification later this year. As such, we will

be able to aggressively pursue EsoCheck commercialization by seeking U.S. Food and Drug Administration (FDA) 510(k) clearance of the cell sampling device and a Laboratory Developed Test designation of the DNA biomarker test," Dr. Aklog said. "We are targeting the first quarter of 2019 for the launch of the first commercial product in the U.S."

#### About GERD, Barrett's Esophagus and Esophageal Cancer

Esophageal adenocarcinoma (EAC) is the most common cancer of the esophagus whose incidence has risen many fold over recent decades. Its prognosis remains dismal with a five-year survival of less than 20%.

The primary cause of EAC cancer is GERD, commonly known as heartburn or acid reflux, where stomach acid refluxes into the lower esophagus. According to published epidemiological data, an estimated 15-30% of adults suffer from GERD symptoms at least once per week. Repeated exposure of the lower esophagus to refluxing acid can lead to Barrett's Esophagus, a transformation of the lower esophageal lining, which is a precursor to precancerous dysplasia and ultimately EAC cancer itself. Nearly all patients diagnosed with EAC cancer have evidence of Barrett's Esophagus, but only 10% have it detected prior to EAC cancer. Barrett's Esophagus can be successfully treated, usually with non-surgical approaches, if detected before EAC cancer develops.

Upper gastrointestinal endoscopy is the standard diagnostic test for Barrett's Esophagus, but it is expensive, invasive and requires intravenous sedation. In addition, microscopic analysis of endoscopic samples depends on assessment by a pathologist, which is also expensive and not fully automatable. As a result, widespread screening for Barrett's Esophagus using endoscopy is neither practical nor cost-effective. There is an urgent unmet clinical need for a highly accurate, non-invasive alternative to endoscopy that utilizes modern automated genetic tools to detect Barrett's Esophagus and prevent highly lethal progression to EAC cancer.

#### The EsoCheck Technology

The EsoCheck kit includes a cell-sampling device consisting of a vitamin pill-sized, silicone-covered capsule containing a small deflated balloon attached to a thin silicone catheter.

In a five-minute, office-based test, the patient swallows the capsule until it reaches the stomach, at which point the balloon is inflated with air. As the catheter is withdrawn, the balloon swabs the lower esophagus for cells. After a specified distance, the balloon is deflated, pulling the cell sample into the capsule, which protects it from dilution or contamination as it passes back through the upper esophagus and mouth.

DNA is extracted from the cells and tested for a panel of methylated DNA biomarkers (mVIM and mCCNA1) developed by the laboratory of EsoCheck co-inventor Sanford Markowitz, M.D., Ph.D., the Ingalls Professor of Cancer Genetics, medical oncologist at University Hospitals Seidman Cancer Center, NCI Outstanding Investigator Awardee, and head of the NIH-Case GI Cancers Program of Research Excellence (GI SPORE) and GI cancer genetics program at the Case Comprehensive Cancer Center.

The group's multicenter clinical study of 408 patients, whose results were recently published in *Science Translational Medicine*, showed that the EsoCheck cell-sampling device and DNA biomarker test was over 90% sensitive and specific at detecting Barrett's Esophagus, and equivalent to endoscopic sampling.

EsoCheck co-inventor, Joseph Willis, M.D., professor of pathology and pathology vice-chair for clinical affairs, at University Hospitals Cleveland Medical Center, is leading the NIH-supported effort to have the EsoCheck DNA biomarker test CLIA certified and designated as a commercial Laboratory Developed Test later this year.

#### Terms of the Definitive Licensing Agreement

Pursuant to the definitive licensing agreement, Case Western Reserve University has granted Lucid Diagnostics Inc., a PAVmed subsidiary, an exclusive perpetual worldwide license of the intellectual property rights for the EsoCheck cell sampling device and DNA biomarker test and all derivatives. The licensed portfolio includes additional biomarkers under a broad field of use for "the detection of changes in the esophagus for screening, diagnosing, disease staging, disease monitoring and disease prognosis."

In return, Case Western Reserve University and its faculty inventors have received a non-cash license fee in the form of a minority equity interest in Lucid Diagnostics, with PAVmed retaining an approximately 82% equity interest. The agreement will be subject to certain regulatory and commercialization milestones, with the university receiving royalties based on revenue and a specified portion of any additional proceeds.

Lucid will be managed by PAVmed as an independently capitalized entity. Its board of directors will initially consist of three PAVmed designees (Dr. Aklog, Dennis M. McGrath, PAVmed Executive Vice President and Chief Financial Officer, and James Cox M.D., PAVmed independent director) and one faculty inventor designee (Dr. Markowitz). Lucid has taken ownership of all EsoCheck related assets including manufacturing equipment, design history files, diagnostic software and protocols.

#### **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 three lead products provide groundbreaking approaches to carpal tunnel syndrome (CarpX™), precancerous conditions of the esophagus (EsoCheck), vascular access (Port IO™) and pediatric ear infections (DisappEAR™). The company is also developing innovative products in other areas, such as medical infusions and tissue ablation, while seeking to further expand its pipeline through engagements with clinician innovators and leading academic medical centers. For further information, please visit [www.pavmed.com](http://www.pavmed.com) [2].

#### **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 the Company'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, factors affecting the timing and effectiveness of the registration statement for our proposed rights offering; general economic and market conditions; the uncertainties inherent in research and development, including the cost and time required to advance our products to regulatory submission; whether regulatory authorities will be satisfied with the design of and results from our pre-clinical studies; whether and when our products are cleared by regulatory authorities; market acceptance of our products once cleared and commercialized; our ability to raise additional funding and other competitive developments. PAVmed has not yet sought or 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 our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A, "Risk Factors," in our 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 us after our most recent Annual Report. We disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our 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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English

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