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# PAVmed Subsidiary Lucid Diagnostics Partners with Fred Hutchinson Cancer Research Center to Evaluate Barrett's Esophagus (BE) Progression Biomarkers Using EsoCheck™

*Lucid secures exclusive option to license biomarker technology to detect progression from nondysplastic to dysplastic BE using EsoCheck to allow curative ablation before deadly esophageal cancer develops*

NEW YORK, Feb. 20, 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"), has entered into a sponsored research agreement with the Fred Hutchinson Cancer Research Center ("Fred Hutchinson") at the University of Washington in Seattle, WA to evaluate Barrett's Esophagus (BE) progression biomarkers in patients using Lucid's EsoCheck™ Esophageal Cell Collection Device with Collect+Protect™ Technology.

The agreement covers a research program entitled "Biomarkers for the Detection of Cancer" led by principal investigator William M. Grady, M.D. AGAF. Dr. Grady is the Rodger Haggitt Professor of Medicine in the Gastroenterology Division of the University of Washington School of Medicine and a Full Member of the Clinical Research Division at Fred Hutchinson. He also serves as the Medical Director of the GI Cancer Prevention Program at the Seattle Cancer Care Alliance.

Pursuant to the agreement, Fred Hutchinson has granted Lucid the exclusive option, exercisable at its sole discretion, to license Fred Hutchinson's candidate BE progression biomarkers during an option period extending twelve months past the completion of a phase II study demonstrating their accuracy. The license would be assignable and exclusive within any field or fields of use in which Lucid reasonably determines it could develop a product that incorporates or utilizes the biomarkers. The license would provide that Lucid would pay to Fred Hutchinson royalties on net sales of products incorporating the BE progression biomarkers at rates not to exceed amounts specified in the agreement.

The research program will include human clinical studies to explore the candidate BE progression biomarkers, which have shown promise in differentiating nondysplastic BE from dysplastic BE and esophageal adenocarcinoma (EAC), on esophageal samples obtained using EsoCheck. Lucid seeks to determine whether a panel of these biomarkers, in conjunction with EsoCheck, can serve as a non-invasive, office-based diagnostic test to monitor patients with nondysplastic BE for evidence of progression to dysplastic BE or EAC. This early detection would permit curative ablation of dysplastic BE before progression to deadly EAC, using esophageal ablation devices such as PAVmed's recently announced EsoCure Esophageal Ablation Device targeted for commercialization in 2021.

"We look forward to working with Dr. Grady and his team at the Fred Hutchinson Cancer Research Center to explore this new EsoCheck application to monitor BE disease progression using Dr. Grady's promising BE progression biomarkers," said Lishan Aklog, M.D., PAVmed's Chairman and Chief Executive Officer and Lucid's Executive Chairman. "I am very pleased that Lucid has also secured the exclusive option to license these biomarkers for commercialization. Several research centers and companies are also pursuing BE progression markers to enhance the surveillance of BE patients and prevent EAC. However, since EsoCheck is the only esophageal cell collection device capable of performing targeted and protected sampling of these esophageal cells, I believe that for any of these candidate BE progression markers to be clinically and commercially viable, they will have to be used on cells collected with EsoCheck."

"I am excited to partner with Lucid on this important research project," said Dr. Grady. "I solicited Lucid because EsoCheck is the only device capable of collecting distal esophageal cells in an anatomically targeted fashion without dilution and contamination from more proximal cells of the esophagus and oropharynx. Anatomically targeted sampling is absolutely necessary for any BE progression biomarker assay to accurately and non-invasively detect disease progression from nondysplastic BE to dysplastic BE and esophageal cancer. Our biomarkers have shown great progress in preliminary work and if they prove accurate in this study, EsoCheck could play an important complementary role to endoscopy in BE monitoring."

PAVmed and Lucid are seeking to offer the only comprehensive and complementary panel of products capable of detecting and treating conditions across the spectrum of conditions from BE to EAC.

Lucid's EsoGuard Esophageal DNA Test and EsoCheck are designed to facilitate the diagnosis of nondysplastic and dysplastic BE – precursors of highly lethal EAC – as well as EAC itself, in patients with chronic heart burn or gastroesophageal reflux disease (GERD). Lucid recently launched EsoGuard as a commercial Laboratory Developed Test (LDT). EsoGuard, which recently received FDA Breakthrough Device Designation, is also the subject of two Lucid-sponsored international multi-center IVD clinical trials, ESOGUARD-BE-1 and 2, in support of an FDA PMA application to establish EsoGuard as an FDA-registered IVD to detect BE in samples collected with EsoCheck in high-risk GERD patients recommended for BE screening by the American College of Gastroenterology.

PAVmed's recently announced EsoCure™ Esophageal Ablation Device with Caldus™ Technology is a disposable single-use thermal balloon ablation catheter designed to advance through the working channel of a standard endoscope. Once cleared and commercialized, EsoCure would allow clinicians to treat dysplastic BE before it can progress to highly lethal EAC and to do so without the need for complex and expensive capital equipment. PAVmed expects to complete development and FDA 510(k) submission of EsoCure by early 2021.

The patent portfolio underlying PAVmed's current license agreement with Case Western Reserve University includes promising candidate BE progression biomarkers in addition to EsoGuard and EsoCheck. A new test designed to detect progression of nondysplastic BE to dysplastic BE using the Fred Hutchinson biomarkers alone or in combination with other biomarkers would effectively complete Lucid-PAVmed's comprehensive and complementary panel of BE-EAC products by providing clinicians with:

1. EsoGuard on samples collected with EsoCheck – a non-invasive diagnostic test designed to detect BE in high-risk GERD patients without a prior diagnosis of BE;
2. New BE progression biomarker test on samples collected with EsoCheck – a non-invasive diagnostic test designed to detect progression of non-dysplastic BE to dysplastic BE and EAC in BE patients as part of a surveillance program with or without periodic endoscopy; and
3. EsoCure - a therapeutic ablation device to treat these dysplastic BE patients prior to further progression to deadly EAC.

**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 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 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 Caldus™ Technology), Minimally Invasive Interventions (CarpX™ Minimally Invasive Device for Carpal Tunnel Syndrome), Infusion Therapy (PortIO™ Implantable Intraosseus Vascular Access Device and NextFlo™ Highly Accurate Disposable Intravenous Infusion Set), and Emerging Innovations (non-invasive laser-based glucose monitoring, NextCath™ self-anchoring cathethers, 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.

**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. 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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