- *Two multinational, multicenter clinical studies launched early 2020 to support regulatory clearance of EsoGuard ™/EsoCheck™ as an FDA-registered In-Vitro Diagnostic (IVD)*

- *Will research Barrett's Esophagus (BE), with and without dysplasia, precursor conditions to highly lethal esophageal cancer (EAC), and EAC itself in patients with gastroesophageal reflux disease (GERD)*

- *Click here for image*

Madrid, Spain, February 11, 2020 – Pivotal today announced that it has been contracted by Lucid Diagnostics Inc., a New York City-based company subsidiary of PAVmed (NASDAQ: PAVM), to provide expert clinical research services for its upcoming clinical studies of its GI *in-vitro* diagnostics EsoGuard™ and EsoCheck™ in the U.S. and Europe.

BE is a change of the normal squamous epithelium of the distal esophagus to a columnar-lined intestinal metaplasia. BE has been detected in approximately 15% of patients with GERD and in approximately 1–2% of population subjects. Recent population studies suggest that prevalence of GERD is increasing.

BE is a known risk factor to develop dysplasia and EAC, which is rapidly increasing in Western Hemisphere countries. This is a highly lethal condition and the main goal of a screening and surveillance program for BE is to identify individuals at risk for progression to EAC and to treat them early.

Currently, endoscopy is the gold standard for surveillance in BE with biopsy sampling. But new diagnostic tests with increased sensitivity and specificity for BE, and less invasive for patients, are needed.

The FDA 510(k)-cleared EsoCheck™Cell Collection Device with Collect+Protect™ technology is a non-invasive device designed to sample cells from a targeted region of the esophagus in a five-minute office-based procedure, without the need for endoscopy. The EsoGuard™ Esophageal DNA Test performs next generation sequencing (NGS) of bisulfite-converted DNA to detect methylation at 31 sites on two genes (VIM and CCNA1). EsoGuard™ has been shown in a 408-patient human study published in Science Translational Medicine to be highly accurate at detecting BE with and without dysplasia, as well as EAC, with greater than 90% sensitivity and specificity.

"We are proud to partner with Dr. Farr and his talented team at Pivotal on these two clinical studies of our revolutionary technologies, EsoGuard™and EsoCheck™," said Lishan Aklog, MD, Lucid Diagnostic's Executive Chairman and parent PAVmed's Chairman and CEO.

“These studies are critical to our efforts to demonstrate that EsoGuard™ and EsoCheck™ have the potential to prevent deaths from esophageal cancer through early detection, monitoring and treatment. We look forward to working with Pivotal to make this happen.”

The aim of these two studies is to determine the operating characteristics (sensitivity, specificity, positive and negative predictive value, and accuracy) of the EsoGuard™ diagnostic assay for the detection of BE on samples collected using EsoCheck™, using EGD findings plus histopathologic examination of biopsies as the reference method, in an at-risk BE population.

“The combined expertise in clinical research excellence of Lucid Diagnostics and Pivotal will enable us to accelerate research and provide access to novel diagnostic tests,” said Dr. Ernesto Estefanía MD, Senior Medical Director, Internal Medicine at Pivotal. “We look forward to positively impacting the lives of people facing Barrett’s Esophagus and its complications.”

EG-CL-101 is a multicenter study that will be conducted to assess the efficacy of EsoGuard™ on samples collected using EsoCheck™, versus EGD, for the diagnosis of BE in an at-risk screened population. A total enrollment of 1000 subjects is expected based on the disease prevalence, in order to have at least 54 patients positive for BE as well as 500 patients negative for BE according to EGD plus biopsy. The study is planned to be launched in the first quarter of 2020.

EG-CL-102 is a multicenter case-control study that will be conducted to assess the efficacy of EsoGuard™ on samples collected using EsoCheck™, versus EGD, for the diagnosis of BE with and without dysplasia, and for EAC. Over 570 subjects will be enrolled in this study. The study is planned to be launched in the first quarter of 2020.

About Lucid Diagnostics

Lucid Diagnostics is a majority-owned subsidiary of PAVmed Inc, a highly differentiated, multi-product medical device company founded and managed by entrepreneurs with a successful track record of developing and commercializing novel medical technologies.

Lucid Diagnostics is developing a revolutionary technology as a non-invasive, office-based targeted cell collection device (EsoCheck ™) and a lab-based, DNA biomarker test (EsoGuard ™) to detect precursor conditions to highly lethal esophageal cancer as well as esophageal cancer itself.

For more information, please visit https://www.luciddx.com/

About Pivotal

Pivotal was founded in 2001 by Dr. Ibrahim Farr on the principle that strategic medical advice and support should be the backbone of all clinical trials. After working for over two decades in the pharmaceutical industry, Dr. Farr recognized the need for a medium-sized CRO with a solid internal medical franchise that could act not only as the "doers" but also as the “co-thinkers” for their clients, through its strategic scientific advice. To date, we are the trusted adviser and counsellor for many companies to deliver maximum value in their drug and medical devices development programs. We are a leading privately held European CRO and, since inception, we have

experienced a fast and steady organic growth in Europe.

Pivotal´s client portfolio spans major pharmaceutical, biotechnological, medical device and nutrition companies, as well as independent investigators and cooperative groups. We have long-standing relations with over 200 clients. Pivotal has extensive experience across major therapeutic areas and phases I to IV. Our highly customized teams bring to each client a combination of broad industry knowledge and operational excellence, to offer our clients fresh perspectives and breakthrough business insights. Additionally, we have built a strong oncology, innovative therapies, rare diseases and early phases hub that enables us to tackle our customers' most difficult challenges, turning recommendations into concrete actions. By remaining true to our core principles and values, our vision is to become our client’s preferred outsourcing solution partner.