



Lucid Diagnostics Licenses Barrett's Esophagus Biomarker Tech from CWRU

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NEW YORK (GenomeWeb) – PavMed announced today that it has completed a definitive licensing agreement with Case Western Reserve University to develop and commercialize CWRU's EsoCheck technology.

Following the licensing agreement, PAVmed's newly formed subsidiary Lucid Diagnostics will own the exclusive global rights to develop and commercialize both the EsoCheck cell sampling device and the DNA biomarker test and all derivatives. The license includes additional biomarkers under a wide field of use to detect "changes in the esophagus for screening, diagnosing, disease staging, disease monitoring, and diseases prognosis," PavMed said.

In return, CWRU 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 82 percent equity interest. The agreement will be subject to certain regulatory and commercialization milestones, with the university receiving royalties based on revenue and an unspecified portion of additional income.

PavMed's EsoCheck technology combines a noninvasive cell sampling device with a DNA biomarker test in order to detect Barrett's esophagus, the primary precursor to a form of esophageal cancer caused by acid reflux.

As part of the five-minute EsoCheckRapid test, the patient swallows a pill-sized capsule that contains a small inflatable balloon attached to a thin catheter. As a clinician extracts the catheter, it swabs the target area for cells while protecting them from contamination. Clinicians then test the sample for a panel of methylated DNA biomarkers for Barrett's esophagus.

"We believe widespread EsoCheck screening has the potential to have... [a] great impact on esophageal cancer... targeting an estimated immediately addressable domestic market of several billion dollars," PavMed Chairman and CEO Lishan Aklog said in a statement.

In addition, the National Institutes of Health has begun a multicenter study on EsoCheck with Case Western Reserve University Hospital and other academic medical centers.

The 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," Amitabh Chak, principal investigator, EsoCheck co-inventor, and CWRU professor, said in a statement.

Aklog added that the EsoCheck device is being manufactured for human use in clinical trials, and that the EsoCheck DNA biomarker test is currently being performed at a reference laboratory that expects to receive CLIA certification later this year. Lucid Diagnostics is aiming for 510(k) clearance from US Food and Drug Administration for its cell sampling device, and is targeting the first quarter of 2019 to launch its first commercial product in the US

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