Mauna Kea Technologies Announces Publication of a Landmark Systematic Review and Meta-Analysis Reinforcing the Diagnostic Accuracy and Clinical Impact of Cellvizio in Upper Gastrointestinal Cancer

Largest ever meta-analysis of upper gastrointestinal endomicroscopy pooling 33 studies and 2,350 patients

Original research conducted and funded by Korea's National Evidence-Based Healthcare Collaborating Agency (NECA)

Authors document major clinical impact in the early diagnosis of esophageal and gastric cancers: dysplasia detected in nearly three times as many patients in Barrett's esophagus surveillance, with 48.5% fewer biopsies per patient

Endomicroscopy characterized as safe and accurate adjunct to standard upper gastrointestinal endoscopy

Systematic reviews with meta-analyses are among the strongest clinical evidence used by guideline committees and payers

Paris and Boston, August 26, 2026 – 5:45 p.m. CEST – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces the publication of a landmark independent systematic review and meta-analysis of probe-based confocal laser endomicroscopy (pCLE) in upper gastrointestinal cancer, conducted and funded by Korea's national health technology assessment agency.

Published as an original research article in *Endoscopy International Open*[1], the meta-analysis pools data from 33 studies involving 2,350 patients, of which 15 focused on esophageal lesions, 16 on gastric lesions and two covering both sites.

The study was conducted and funded by the Division of Health Technology Assessment Research of Korea's National Evidence-Based Healthcare Collaborating Agency (NECA), the country's national health technology assessment organization. Its protocol was defined in advance by a dedicated evaluation committee assembled by the agency, comprising pathologists, gastroenterologists, methodological experts and biostatisticians, and the work followed Cochrane and PRISMA methodology, with QUADAS-2 quality assessment, bivariate random-effects modelling of pooled diagnostic accuracy, pre-specified sensitivity analyses and formal testing for publication bias.

Co-authors are affiliated with NECA, CHA University School of Medicine, Asan Medical Center (University of Ulsan College of Medicine), Yonsei University College of Medicine and Seoul St. Mary's Hospital (The Catholic

[1] J.-Y. Lee, S.-H. Lee, Y.-G. Ji, H.-Y. Jung, J.-S. Koo, J.-M. Park. *Confocal laser endomicroscopy for upper gastrointestinal neoplasia: Systematic review and meta-analysis.* **Endoscopy International Open.** 2026;14:a28631407. DOI: 10.1055/a-2863-1407

University of Korea College of Medicine). The authors declare no conflicts of interest. Mauna Kea Technologies played no role in the design, conduct, funding, or interpretation of the review.

Enhanced lesion detection and reduced biopsy burden

In Barrett's esophagus surveillance, adding pCLE to high-definition white-light endoscopy increased per-patient dysplasia detection to 28% of patients (14 of 50) from 10% (5 of 50) ($p = 0.04$). Among patients with poorly cohesive gastric adenocarcinoma, pCLE-guided biopsies identified malignant tissue in 65% of patients (19 of 29), versus 30% (10 of 32) with standard white-light-directed biopsies ($p = 0.01$). In a randomized trial in suspected gastric precancerous lesions, combining pCLE with flexible spectral imaging color enhancement (FICE) produced a diagnostic yield per biopsy of 75.1%, versus 31.5% with FICE alone ($p < 0.001$).

The same randomized study found that pCLE-guided targeting reduced the mean number of biopsies per patient by 48.5%, from 6.8 to 3.5 ($p < 0.001$). In a selected cohort of 13 patients with Barrett's esophagus and subtle mucosal irregularities without a discrete macroscopic lesion, adjunctive pCLE altered real-time therapeutic management in 69.2% of cases (9 of 13) either prompting endoscopic resection where higher-grade disease was suspected or avoiding unnecessary resection or ablation where neoplasia was not supported.

Diagnostic performance

The authors conclude that pCLE is a safe and accurate adjunct to standard upper gastrointestinal endoscopy, particularly when lesion conspicuity is low or histologic confirmation is important. In studies comparing the two directly, adjunctive pCLE consistently showed higher sensitivity than white-light endoscopy alone with comparable or modestly improved specificity, underscoring its role as an adjunctive characterization tool rather than a replacement for high-quality conventional endoscopy.

Compared with histopathology, pooled sensitivity was 89% for both esophageal and gastric neoplasia; pooled specificity was 79% for esophageal lesions and 95% for gastric lesions. Discrimination was strong and consistent for high-grade dysplasia and overtly neoplastic lesions, with pooled sensitivity of 88% and specificity of 87%. The authors note that pooled estimates, particularly the high specificity observed for gastric lesions, should be interpreted with appropriate caution given potential small-study effects, and that the evidence base is drawn largely from high-volume academic centers.

Regulatory and reimbursement status

Confocal laser endomicroscopy is already established in the indications covered by this meta-analysis. In Korea, the technology received a positive health technology assessment from NECA in 2018, and coverage of the GastroFlex™ UHD probe and of the confocal endomicroscopy procedure in esophageal and gastric indications was ratified by the Ministry of Health and Welfare in February 2020. In the United States, optical endomicroscopy (OE) is performed and reported under dedicated Category I CPT® codes, and upper gastrointestinal applications represent the core of the Company's recurring per-procedure revenue.

Systematic reviews with meta-analyses are among the strongest clinical evidence used by clinical guideline committees and by payers assessing coverage.

Sacha Loiseau, Ph.D., Chairman and Chief Executive Officer of Mauna Kea Technologies, said: *"The incidence of esophageal adenocarcinoma in the United States has had a dramatic 5- to 6-fold increase in the past decades, and millions of Americans with non-diagnosed Barrett's esophagus are at risk. We have designed and developed Cellvizio to empower physicians with cellular vision, enabling them to see what really matters; this is our purpose. For nearly fifteen years, well designed clinical trials have shown that the use of Cellvizio as an adjunct to regular and advanced endoscopy considerably enhanced diagnostic performance and patient management. Today, this landmark independent review and meta-analysis of 33 studies and 2,350 patients, funded by a national assessment agency with no industry involvement, reinforces that value proposition and details the major clinical impact that the use of Cellvizio provides. I believe this will help broaden reimbursement coverage and clinical adoption for Cellvizio in the United States, our primary market."*

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio® platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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