Cellvizio[®] Now Recommended in New European Society of Gastrointestinal Endoscopy Technical Guideline for Pancreatic Cyst Diagnosis

ESGE, Europe's leading endoscopy society, endorses Cellvizio® as a key tool for improving pancreatic cyst diagnostic accuracy, marking a major step towards broader commercial adoption

Paris and Boston, March 3, 2025 – 5:45 p.m. CET – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio[®], the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that the European Society of Gastrointestinal Endoscopy (ESGE) has issued a recommendation for the use of needle-based confocal laser endomicroscopy (nCLE) with Cellvizio[®] for the characterization of pancreatic cystic lesions (PCLs)¹. This recognition highlights the potential of nCLE to enhance the accuracy of pancreatic cyst diagnoses in centers with adequate expertise, supporting its integration into standard clinical practice.

Bertrand Napoléon, M.D., Department of Gastroenterology at the Jean Mermoz Private Hospital in Lyon, France, commented: "The diagnostic pathway for pancreatic cystic lesions has always been a clinical challenge, as conventional tools and techniques still leave a large amount of uncertainty about the nature and classification of certain cysts. The addition of nCLE to the diagnostic pathway significantly improves diagnostic accuracy and has a direct impact on patient outcomes. The inclusion of nCLE in ESGE's best practice guidelines for the management of pancreatic cysts is a logical extension of the scientific data obtained over the last ten years."

ESGE suggests the use of nCLE to differentiate between mucinous and non-mucinous pancreatic cysts, acknowledging the technology's ability to provide real-time, high-resolution imaging of tissue and vascular structures. The recommendation is based on a large body of clinical evidence demonstrating nCLE's diagnostic accuracy compared to conventional endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) alone.

Several multi-center studies have reported high diagnostic accuracy with nCLE, including one study presented at Digestive Disease Week[®] 2024 demonstrating very high sensitivity and diagnostic accuracy of EUS-nCLE for classifying mucinous vs. non-mucinous PCLs of 98% and 97%, respectively, compared to 77% and 80% for CEA + cytology + glucose. Further research has shown that nCLE improves interobserver agreement and intraobserver reliability in diagnosing mucinous lesions, serous cystadenomas, and pseudocysts, which today remains challenging with conventional diagnostic methods. Additionally, cost-benefit analyses demonstrate that integrating nCLE into PCL management reduces unnecessary surgeries by 23% and decreases overall clinical costs by 13%.

Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies, concluded: "After a decade of development, we have demonstrated the unique ability of Cellvizio to accurately characterize pancreatic cysts with near-perfect accuracy. This recognition from ESGE marks a turning point, underscoring the critical role

¹ <u>https://www.esge.com/endoscopic-ultrasound-guided-tissue-sampling-esge-technical-review</u>

that nCLE with Cellvizio can play in transforming pancreatic cyst diagnosis. For patients, this means fewer unnecessary surgeries on indeterminate cysts, faster and more accurate diagnoses, and ultimately better outcomes. For healthcare providers, integrating nCLE into routine practice represents a major leap forward in precision medicine. With pancreatic cysts affecting millions worldwide and current diagnostic tools leaving too much uncertainty, this recommendation paves the way for large-scale deployment and will be a key driver in securing reimbursement across several countries. 2025 is off to a strong start and is set to be a milestone year for this indication. Some highly anticipated results from the CLIMB study - the largest clinical study for this indication - conducted in 14 centers in the United States, set to be unveiled at Digestive Disease Week® 2025, will definitively establish our technology as the gold standard worldwide for pancreatic cyst characterization."

About Pancreatic Cysts

The prevalence of pancreatic cystic lesions in the adult asymptomatic population ranges from 2.4% to 24.3%. The large majority of pancreatic cystic lesions are discovered through incidental imaging, and it is estimated that 40% of cysts with no risk of carcinogenesis are operated on unnecessarily. More accurate classification methods, including risk stratification, are therefore needed earlier in the patient's diagnostic workup. Conventional diagnostic testing involves performing an endoscopic ultrasound (EUS) and then collecting and testing the cyst fluid through fine needle aspiration (FNA). In some advanced facilities, next generation sequencing (NGS) of cellular DNA may be performed to provide additional data.. Although most facilities employ a combination of a range of conventional diagnostic methods, sensitivity, specificity, and accuracy remain insufficient, potentially exposing patients to unneeded surgical procedures.

About ESGE

The European Society of Gastrointestinal Endoscopy (ESGE) represents national societies of endoscopy in Europe, the Mediterranean and North Africa. One society from any of these countries is eligible for membership, and one representative from each national member society may vote in the General Assembly which meets annually at the time of the ESGE Days congress. Currently the ESGE is comprised of 41 gastrointestinal societies (ESGE National Member Societies) and individual members. Two ESGE Individual Members with voting power are elected by ESGE.

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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