Mauna Kea Technologies Announces Major AI Breakthrough with Cellvizio in Pancreatic Cystic Lesion Risk Stratification

Cellvizio® technology combined with AI outperforms human experts in pancreatic cyst risk stratification, a major breakthrough for patient management

Results build on new CLIMB study data recently presented at Digestive Disease Week® (DDW)[1] confirming Cellvizio®'s unmatched accuracy in pancreatic cyst diagnosis

Paris and Boston, June 2, 2025 – 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 a significant advancement with the results of a landmark study published in the peer-reviewed journal *Pancreatology*. The research, titled "*Towards Automating Risk Stratification of Intraductal Papillary Mucinous Neoplasms: Artificial Intelligence Advances Beyond Human Expertise with Confocal Laser Endomicroscopy[2]*", demonstrates that Artificial Intelligence (AI) model combined with Cellvizio® needle-based confocal laser endomicroscopy (nCLE) technology significantly outperforms human experts in risk stratification of Intraductal Papillary Mucinous Neoplasms (IPMNs), a common type of pancreatic cyst.

The study aimed to compare the performance of 16 nCLE human experts with a novel AI algorithm (nCLE-AI) specifically designed for the sub-classification of a type of pancreatic cystic lesion with malignant potential. These findings build on the CLIMB study data presented this year at DDW, which demonstrated strong diagnostic performance of needle-based confocal laser endomicroscopy in differentiating benign from malignant or pre-malignant pancreatic cysts. Indeed, the latest results from the CLIMB study - spanning 17 endosonographers across 14 centers - have further reinforced the significantly superior diagnostic accuracy of Endoscopic Ultrasound-guided nCLE (EUS-nCLE) compared to the current standard of care[3].

---

[1] [Press release as of May 6, 2025](#)
[2] https://doi.org/10.1016/j.pan.2025.05.011
[3] https://doi.org/10.1016/j.gie.2025.03.851

DDW 2025 CLIMB Study Results			
	Sensitivity %	Specificity %	Accuracy %
EUS-nCLE (n = 187)	96.8	93.5	95.2
CEA and/or Cytology or Glucose (n = 161)	82.2	84.5	83.2

"This study marks a pivotal moment in our ability to accurately risk stratify pancreatic cysts. The nCLE-AI model has shown remarkable potential to not only enhance diagnostic accuracy beyond current expert capabilities but also to standardize the interpretation of nCLE imaging," said **Dr. Somashekar (Som) Krishna, Professor of Medicine and Director of Advanced Endoscopy at The Ohio State University Wexner Medical Center**, **lead author of the publication**. *"By providing a more precise and objective assessment, this technology can significantly aid clinical decision-making, helping to ensure that patients at high risk receive timely intervention while those with low-risk cysts may avoid unnecessary surveillance or surgery."*

The results of the study on risk stratification associated with IPMNs cysts with malignant potential, detailed in the table below, show that the nCLE-AI model combined with revised Fukuoka Criteria achieves an Area Under the Curve (AUC) of 0.85, with a sensitivity of 78% and a specificity of 78%. This performance is significantly superior to that of human experts using the same criteria (AUC 0.64; $p<0.01$) and represents an improvement over the nCLE-AI model alone ($p=0.02$), clearly demonstrating the superiority of the AI-augmented approach for enhancing the detection of malignant cysts that need immediate intervention. The AI model continues to improve rapidly with additional nCLE sequences and data.

Results on Cyst Risk Stratification for IPMNs				
Analysis Method	AUC (Area Under the Curve)	Sensitivity	Specificity	Interobserver Agreement (IOA) (κ)
Human experts (nCLE alone)	0.59	58%	59%	Fair (κ=0.29)
Human experts (nCLE + revised Fukuoka Criteria)	0.64	72%	57%	Fair (κ=0.36)
nCLE-AI model (alone)	0.70	87%	54%	Not applicable
nCLE-AI model + revised Fukuoka Criteria (combined)	**0.85**	**78%**	**78%**	**Not applicable**

Sacha Loiseau, Ph.D., Chairman and Chief Executive Officer of Mauna Kea Technologies, stated: *"These latest results, published by a group of highly skilled interventional endoscopists from multiple countries and institutions, under the exceptional leadership of Dr. Krishna, materialize our vision of nCLE enhanced by AI models, whether developed internally or by academic partners. Adding AI will certainly lead to a broader adoption of nCLE in the community of interventional endoscopists but will also open the door to risk stratification strategies, which are completely absent in today's standard of care. This strongly reinforces our conviction that nCLE is playing a pivotal role in the diagnosis and management of patients at risk of pancreatic cancer."*

***

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 misclassified cysts and unneeded surgical procedures

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.

Disclaimer

This press release contains forward-looking statements about Mauna Kea Technologies and its business. All statements other than statements of historical fact included in this press release, including, but not limited to, statements regarding Mauna Kea Technologies' financial condition, business, strategies, plans and objectives for future operations are forward-looking statements. Mauna Kea Technologies believes that these forward-looking statements are based on reasonable assumptions. However, no assurance can be given that the expectations expressed in these forward-looking statements will be achieved. These forward-looking statements are subject to numerous risks and uncertainties, including those described in Chapter 2 of Mauna Kea Technologies' 2024 Annual Report filed with the *Autorité des marchés financiers* (AMF) on April 30, 2025, which is available on the Company's website (www.maunakeatech.fr), as well as the risks associated with changes in economic conditions, financial markets and the markets in which Mauna Kea Technologies operates. The forward-looking statements contained in this press release are also subject to risks that are unknown to Mauna Kea Technologies or that Mauna Kea Technologies does not currently consider material. The occurrence of some or all of these risks could cause the actual results, financial condition, performance or achievements of Mauna Kea Technologies to differ materially from those expressed in the forward-looking statements. This press release and the information contained herein do not constitute an offer to sell or subscribe for, or the solicitation of an order to buy or subscribe for, shares of Mauna Kea Technologies in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. The distribution of this press release may be restricted in certain jurisdictions by local law. Persons into whose possession this document comes are required to comply with all local regulations applicable to this document.