Mauna Kea Technologies announces two new publications demonstrating the efficacy, safety and accuracy of Cellvizio® for Pancreatic Cyst Evaluation

Further peer-reviewed evidence that using Cellvizio as an adjunct to the standard of care can significantly improve the speed and accuracy of reaching a conclusive diagnosis

Paris and Boston, November 4, 2020 – 6.00 PM CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced the publication of a peer-reviewed meta-analysis and of an international Delphi consensus report based on a systematic, evidence-based review of endoscopic ultrasound (EUS) guided needle-based confocal laser endomicroscopy for pancreatic cystic lesion (PCL) evaluation.

The first publication entitled "Needle-based Confocal Laser Endomicroscopy in Pancreatic Cysts: a Meta-Analysis", was published in the European Journal of Gastroenterology & Hepatology (2020, DOI: 10.1097/MEG.0000000000001728). Ten studies enrolling 536 patients were included and the authors evaluated diagnostic accuracy, pooled sensitivity, specificity, and mean procedural time. The meta-analysis concluded that confocal laser endomicroscopy "clearly outperformed" endoscopic ultrasound fine-needle aspiration (EUS-FNA) in terms of diagnostic accuracy (odds ratio 3.94, 1.58–9.82; P = 0.003) and supports the use of needle-based confocal laser endomicroscopy as a safe and effective tool in the diagnostic algorithm of pancreatic cysts.

The second publication entitled "Confocal Endomicroscopy for the Evaluation of Pancreatic Cystic Lesions: A Systematic Review and an International Delphi Consensus Report", was published in the peer-reviewed journal Endoscopy International Open (2020, DOI: 10.1055/a-1229-4156) and was based on consensus statements from an international panel of 15 experts in pancreatic disease that conducted evidence-based reviews of the applications, outcomes, procedural processes, indications, training, and credentialing of EUS-nCLE in the management of PCLs. The consensus report reflected a high level of agreement pertaining to expert consensus statements and established that EUS-guided nCLE is a minimally invasive procedure that improves evaluation of PCLs and "should be systematically considered when EUS-FNA is indicated for PCL evaluation." The consensus report also concluded that the use of nCLE as an adjunct to standard EUS-FNA could positively impact patient management and improve healthcare resource utilization by reducing the number of misdiagnoses and preventing redundant follow-up investigations and unnecessary surgery.

"The new meta-analysis and consensus report provide further support that Cellvizio plays a key role in the evaluation of pancreatic cysts and can significantly improve the speed and accuracy of reaching a conclusive diagnosis," said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. "The level of clinical evidence and support suggests that hospitals performing endoscopic evaluation of pancreatic cysts would benefit their patients by incorporating Cellvizio as part of the management of their patients. This represents approximately 75,000 procedures in the US alone. We look forward to the growing adoption of Cellvizio for this important application."

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company's flagship product, Cellvizio®, has received clearance/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, and China. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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