



MAUNA KEA TECHNOLOGIES ANNOUNCES PUBLICATION OF CONFIRMATION DATA ON THE VALUE OF ENDOMICROSCOPY FOR THE CHARACTERIZATION OF PANCREATIC CYSTIC NEOPLASMS

Investigator-Initiated DETECT Study shows benefits of using Cellvizio to safely differentiate the nature of pancreas cysts with high specificity and accuracy

Findings from research team at UC Irvine published in peer-reviewed journal "Gastrointestinal Endoscopy"

PARIS, March 25, 2015 – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, today announced publication of a pilot monocentric study by Dr Y. Nakai *et al*, University of California Irvine Medical Center, Orange, CA. The study results show that needle-based confocal endomicroscopy (nCLE) procedures safely performed with Cellvizio were successfully able to differentiate mucinous from non-mucinous pancreatic cysts with a high degree of accuracy. Results were published recently in the peer-reviewed journal *Gastrointestinal Endoscopy*.

In an article entitled: "Diagnosis of pancreatic cysts: EUS-guided, through-the-needle confocal laser-induced endomicroscopy and cystoscopy trial: DETECT study », the research team led by Dr Kenneth J. Chang, at UC Irvine report that the use of Cellvizio demonstrated 100% positive predictive value and 100% specificity in characterizing mucinous cysts thanks to the visualization of papillary projections, also called papillae. Researchers were able to confirm the classification of these cysts as mucinous (IPMN) by either surgery or standard tests (e.g, EUS, CEA, cytology, amylase) in a high-certainty diagnosed sub-population. Authors showed nCLE-accuracy data at a level of 89% using this criteria in pancreatic cysts.

"With nCLE, we were able to confirm the mucinous nature of pancreatic cysts based on observation of papillary projections or dark rings that are visible only with the Cellvizio nCLE technology. We were one of the pioneer centers using this advanced technology for this application in the U.S.," said Dr Chang, Chief of Gastroenterology and Hepatology and Director of the Comprehensive Digestive Disease Center at UC Irvine, adding, "The ability to rapidly confirm a diagnosis using nCLE means that we may be able to offer better options for these patients and reduce or eliminate the need for patients to advance to surgery when they don't need it."

"The findings from the DETECT study reinforce the evidence gathered on the use of nCLE in characterization of pancreatic cysts as shown by the recently published clinical trials results INSPECT (Konda et al, 2013, Endoscopy) and CONTACT1 (Napoléon et al, 2014, Endoscopy)." said Sacha Loiseau, Ph.D, CEO and founder of Mauna Kea Technologies "We are very pleased that independent users from leading medical research centers are continuing to add to the body of clinical evidence demonstrating the benefits of nCLE for patients suffering from pancreatic lesions. These patients need more precise answers and better orientation to therapeutic options, and our Cellvizio nCLE technology is helping physicians around the world to do just that."

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. The company's flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers with high-resolution cellular imaging of internal tissues. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with practically all endoscopes. Cellvizio has 510(k) clearance from the United States Food and Drug Administration and CE Marking in the European Union for use in the gastrointestinal tract and the urinary and respiratory systems, for endoscopic exploration of the biliary and pancreatic ducts, and for fine-needle aspiration procedures. Cellvizio also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For more information on Mauna Kea Technologies, visit www.maunakeatech.com



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