



NEW PEER-REVIEWED PUBLICATION REPORTS FURTHER EXTERNAL VALIDATION OF UNMATCHED CELLVIZIO ENDOMICROSCOPY PERFORMANCE AND INTER-OBSERVER AGREEMENT IN THE CHARACTERIZATION OF PANCREATIC CYSTS

Clinical study published in *GI Endoscopy* this month, performed by the Wexner Medical Center at Ohio State University, a National Pancreas Foundation Center of Excellence

Blinded trial shows 95% accuracy of Cellvizio for malignant pancreatic cysts and 98% for benign pancreatic cysts, both with near-perfect inter-observer agreement and intra-observer reliability

Paris, France and Cambridge, MA, USA, March 27, 2017 - Mauna Kea Technologies (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, today announced the publication of a new study highlighting the strong performance of needle-based confocal laser endomicroscopy (nCLE) in the diagnosis of pancreatic cysts. The study outcomes¹ were published online in the March 2017 edition of *Gastrointestinal Endoscopy*, the official peer-reviewed journal of the American Society for Gastrointestinal Endoscopy (ASGE), and includes nCLE images and video referenced in the study.

In this investigator-sponsored study, six physicians from different countries, experienced in nCLE, blinded to all clinical data, reviewed nCLE images of pancreatic cystic lesions from 29 subjects with surgical (n=23) or clinical (n=6) confirmed diagnostics. After 2 weeks, the assessors reviewed the same images in a different order. The results show that:

- nCLE provided 95% sensitivity, 94% specificity, and 95% accuracy in the diagnosis of malignant pancreatic cysts, with highly aligned inter-observer agreement and intra-observer reliability, demonstrated by K statistics ($K = 0.81$ and $K = 0.86$, both almost perfect, respectively).
 - These results suggest that thanks to nCLE, patients with malignant pancreatic cysts can be diagnosed earlier and avoid repeated unnecessary procedures that are commonly performed.
- The same procedure performed on benign pancreatic cysts exhibited even stronger performances with 98% sensitivity, 99% specificity, and 98% accuracy in the diagnosis of and also with highly aligned inter-observer agreement and intra-observer reliability for recognizing characteristic image pattern of benign cysts, demonstrated by Kappa statistics ($K = 0.83$ and $K = 0.85$, both almost perfect, respectively).
 - The ability of nCLE to accurately diagnose benign pancreatic cysts can spare patients the need to undergo unnecessary invasive diagnostic procedures and undue surgery, which is currently performed on as many as 40% of patients and associated with high morbidity.

Sacha Loiseau, Ph.D., Founder and Chief Executive Officer of Mauna Kea Technologies, commented, “The results from this well-designed independent, international study, confirm the unmatched level of sensitivity and specificity for characterizing cystic lesions of the pancreas. Millions of Americans have a pancreatic lesion and tens of thousands will undergo an unnecessary interventional procedure, including surgeries. These results confirm that, as we have seen with other large studies, a majority of these procedures could be avoided with a single Cellvizio procedure performed during an endoscopic ultra-sound examination. In addition, this study confirms the near perfect inter-observer agreement among properly trained healthcare professionals using Cellvizio in this application. This data will contribute to our ongoing efforts to increase adoption of Cellvizio for core GI applications in the U.S. under our new pay-procedure business model.”

The Wexner Medical Center at Ohio State University was recently recognized by The National Pancreas Foundation as Pancreas Center of Excellence. This designation recognizes excellence across multiple disciplines, which focus on patient-centered care of patients with pancreatic disorders. The approval process followed an extensive audit of the institution’s resources for patient management. OSU’s Wexner Medical



Center was recognized among 30 other centers nationwide, and was the only pancreatic disorder adult-center in the state of Ohio².

Reference

1. Krishna, S. et al. Needle-based confocal laser endomicroscopy for the diagnosis of pancreatic cystic lesions: an international external interobserver and intraobserver study (with videos). *Gastrointestinal Endoscopy*. DOI: <http://dx.doi.org/10.1016/j.gie.2017.03.002>
2. Ohio State University website: <https://internalmedicine.osu.edu/digestivediseases/about-the-division/pancdisease/>

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 to sell a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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Mauna Kea Technologies

Benoit Jacheet
CFO
investors@maunakeatech.com

United States

Zack Kubow / Lee Roth
The Ruth Group
646-536-7020 / 7012
zkubow@theruthgroup.com
lroth@theruthgroup.com

U.S. Media

Kirsten Thomas
The Ruth Group
508-280-6592
kthomas@theruthgroup.com

France and Europe

NewCap - Investor
Relations
Florent Alba
+33 (0)1 44 71 94 94
maunakea@newcap.fr