## TWO NEW PUBLICATIONS FROM LEADING TEAM IN CHINA PRESENT DATA FROM LARGE CLINICAL TRIALS HIGHLIGHTING ADVANTAGES OF CELLVIZIO IN DIAGNOSIS OF GASTRIC AND ESOPHAGEAL CANCERS

### Clinical trials at Qilu Hospital enrolled 356 and 240 patients respectively

# Publications in peer reviewed journals *Gastrointestinal Endoscopy* and *Journal of Clinical Gastroenterology* highlight diagnostic value of confocal laser endomicroscopy in treatment of highly-prevalent pathologies in China and across Asia

**PARIS, March 3, 2015** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio<sup>®</sup>, the multidisciplinary confocal laser endomicroscopy platform, today announced that clinicians from leading center for endomicroscopy in China have just published two new large prospective studies highlighting the advantages of Cellvizio probe-based confocal laser endomicroscopy (pCLE) in the diagnosis of esophageal and gastric cancers. Results of a study of more than 240 patients with gastric cancers were published in the Journal of Clinical Gastroenterology while results of a second study on 356 patients with esophageal squamous neoplasia (ESN) were published in the journal Gastrointestinal Endoscopy.

In the first study, the team from Qilu Hospital at Shandong University in China presented results of a prospective Phase 2 trial showing that the use of pCLE significantly improves specificity of diagnosis in gastric cancer thanks to a new classification of pCLE interpretation criteria. Clinicians were able to diagnose with very high accuracy a variety of common gastric conditions, ranging from atrophic gastritis to intestinal metaplasia and cancer. In particular, physicians using pCLE diagnosed neoplasia with 89.89% sensitivity and 99.44% specificity. In addition, the inter-observer agreement for the image interpretation criteria developed for neoplasia was proven to be substantial, further validating the use of this new classification.

"Gastric cancer is a significant health issue all around Asia-Pacific and especially in China. Challenges with diagnosis often mean that patients are unable to get an early and accurate diagnosis, putting them at risk." said Professor Yan-Qing Li, MD, PhD, Director of the Department of Gastroenterology and Vice-President of Shandong University Qilu Hospital "The ability of pCLE to improve both speed and accuracy in early diagnosis represents a major advantage in the treatment of gastric cancers in the years ahead."

In the second study, clinicians assessed the diagnostic value of pCLE in a sub-group of 91 patients among a population of 356 patients with early stage ESN. Within this population the use of pCLE was shown to support the diagnosis of ESN with very high levels of sensitivity (95%), specificity (91%), positive predictive value (87%) and negative predictive value (96%). Total accuracy was 92.3%.

"These highly positive results indicate that pCLE can play an important role in diagnosing and differentiating ESN. Rapid and accurate detection and differentiation of ESN is essential to improve patient outcomes, and use of pCLE with Cellvizio to support diagnosis can play a critical role in helping more patients access appropriate care faster," added Prof. Yan-Qing Li.

"These landmark research studies in China represent a new level of confirmation of the advantages of Cellvizio in the diagnosis of two types of cancer that are especially prevalent in China and throughout Asia. These excellent results on such large populations will support the wider adoption of Cellvizio and its reimbursement in China. We are proud to see how the Qilu Hospital, already the largest pCLE center in China and home of several clinical studies on pCLE, is constantly exploring new indications for our technology." concludes Sacha Loiseau, CEO and Founder of Mauna Kea Technologies.





#### **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<sup>®</sup>, 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 further information on Mauna Kea Technologies, visit www.maunakeatech.com

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