



## MAUNA KEA TECHNOLOGIES ANNOUNCES PEER-REVIEWED PUBLICATION OF KEY MULTICENTER RANDOMIZED CONTROLLED TRIAL DEMONSTRATING IMPROVED EARLY STOMACH CANCER DETECTION WITH CELLVIZIO

*Results from 238-patient randomized controlled clinical trial published in Endoscopy*

*Diagnostic yield more than doubled with Cellvizio while number of necessary biopsies reduced by half and no change in procedure time*

**Paris, August 2, 2017 – Mauna Kea Technologies** (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy (CLE) platform, today announced the peer-reviewed publication of a clinical study<sup>1</sup> demonstrating improved early stomach cancer detection with Cellvizio<sup>2</sup> in *Endoscopy*, the official journal of the European Society of Gastrointestinal Endoscopy (ESGE) and affiliated societies.

The new data builds on a [recently published meta-analysis](#)<sup>3</sup> of Cellvizio in stomach cancer and further establishes the superiority of biopsies guided by a combination of endoscopic imaging with Flexible spectral Imaging Colour Enhancement (FICE) and probe-based confocal laser endomicroscopy (pCLE) with Cellvizio, compared to standard FICE without pCLE for in vivo detection of pre-cancerous and cancerous gastric lesions.

According to *JAMA Oncology*<sup>4</sup>, the annual incident rate of stomach cancer exceeds 1.3 million cases worldwide, making it the 3rd most common malignancy globally by incidence and mortality (after cancers of the lung and the breast). An estimated 1 in 27 men and 1 in 68 women will develop stomach cancer before the age of 79 years.

Led by principal investigator Pr. Yan-Qing Li, Chief physician and Vice President of Qilu hospital of Shandong University, this key study enrolled 238 patients who were randomized in two groups (FICE-guided pCLE with targeted biopsies (using a Gastroflex UHD Confocal Miniprobe) or FICE with standard biopsies) at four clinical institutions in China. The diagnostic yield of gastric intestinal metaplasia (GIM), gastric intraepithelial neoplasia (GIN), and early gastric cancer (EGC) was compared between the two groups as a main outcome. Secondary outcomes include the number of necessary biopsies to achieve diagnosis and time taken for the procedure.

The key results from the study are as follows:

- Doubled diagnostic yield: On a per-biopsy analysis, FICE-guided pCLE with targeted biopsies more than doubled the diagnostic yield of GIM/GIN/EGC vs. FICE with standard biopsies, from 31.5% to 75.1% (p< 0.001).
- Reduced number of necessary biopsies by half: FICE-guided pCLE with targeted biopsies led to a 48.5% decrease in the number of biopsies per patient vs. FICE with standard biopsies (p<0.001).
- No change in procedure-time: Procedure time was not significantly different between the 2 groups (17 minutes in the pCLE group vs. 16 minutes in the control group).
- Confirmed clinical performance of Cellvizio:
  - Sensitivity, specificity, positive predictive value and negative predictive value of pCLE were 87.5%, 98%, 87.5% and 98% for GIN and 95%, 94.6%, 90.5% and 97.5% for GIM.
  - Inter-observer agreement and intra-observer agreement were excellent with kappa-values of 0.83 and 0.89, respectively.

The authors concluded, “Real-time pCLE and targeted biopsies after FICE improved the diagnostic yield for the detection of GIM, GIN, and EGC, and only required about half the number of biopsies versus FICE with standard biopsies. This may allow for a better regimen for endoscopic surveillance and subsequent treatment of patients

<sup>1</sup> ClinicalTrials.gov (NCT02515721)

<sup>2</sup> Xiu-Li Zuo et al. Probe-based endomicroscopy for in vivo detection of gastric intestinal metaplasia and neoplasia: a multicenter randomized controlled trial. *Endoscopy*. Published online 2017 DOI: 10.1055/s-0043-115382

<sup>3</sup> Press-release Mauna Kea Technologies – March 2<sup>nd</sup>, 2017

<sup>4</sup> Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global Burden of Disease Study - *JAMA Oncol.* 2017 Apr 1;3 (4):524-548.



with premalignant and malignant gastric abnormalities. All pCLE procedures were performed safely and successfully in participating patients.”

Sacha Loiseau, Ph.D., Founder and Chief Executive Officer of Mauna Kea Technologies, said, “This paper is a key milestone for demonstrating the role for Cellvizio in the early detection of gastric cancer. We are grateful to Pr. Yan-Qing Li, Pr. Xiu-Li Zuo and their team for their leadership in completing this important clinical study.”

**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](http://www.maunakeatech.com)

**United States**

Zack Kubow / Lee Roth  
The Ruth Group  
646-536-7020 / 7012  
[zkubow@theruthgroup.com](mailto:zkubow@theruthgroup.com) [lroth@theruthgroup.com](mailto:lroth@theruthgroup.com)

**U.S. Media**

Kirsten Thomas  
The Ruth Group  
508-280-6592  
[kthomas@theruthgroup.com](mailto:kthomas@theruthgroup.com)

**France and Europe**

NewCap - Investor Relations  
Florent Alba  
+33 (0)1 44 71 94 94  
[maunakea@newcap.eu](mailto:maunakea@newcap.eu)

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