

## MAUNA KEA TECHNOLOGIES ANNOUNCES POSITIVE RESULTS FROM *FOCUS* PIVOTAL CLINICAL TRIAL ON USE OF CONFOCAL LASER ENDOMICROSCOPY IN BILIARY CANCER DETECTION

*Results published in peer-reviewed journal Gastrointestinal Endoscopy accompanied by editorial noting that the study “pushes the boundaries of diagnosis in indeterminate biliary strictures”*

*Study results support the use of endomicroscopy with Cellvizio for the evaluation of indeterminate biliary strictures*

**PARIS, January 27, 2015** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, today announced publication of the final results of the multi-center international prospective *FOCUS* clinical trial assessing the use of probe-based confocal laser endomicroscopy (pCLE) in the diagnosis of biliary cancer during endoscopic retrograde cholangio-pancreatography (ERCP).

In the *FOCUS* study a total of 112 patients with indeterminate biliary strictures were treated in six centers around the world. Results were published in the peer-reviewed journal *Gastrointestinal Endoscopy*, the official journal of the *American Society of Gastrointestinal Endoscopy (ASGE)*.

Adam Slivka, M.D., Professor of Medicine and Associate Chief, Division of Gastroenterology, Hepatology & Nutrition at University of Pittsburgh Medical Center, and principal investigator of the *FOCUS* study, said: “This important study prospectively and statistically confirms the superiority of pCLE-enhanced ERCP over traditional ERCP. This provides strong support for pCLE to be added to the armamentarium of therapeutic endoscopists when performing ERCP and evaluating patients with indeterminate biliary strictures.”

The *FOCUS* trial evaluated the diagnostic performance of pCLE with Cellvizio for the characterization of biliary strictures and thus for the presence of biliary cancer (cholangiocarcinoma). Results show a very significant improvement in the sensitivity of detection of cholangiocarcinoma, from 56% for biopsies to 89% for pCLE.

Among the 112 patients enrolled in this study, pCLE correctly diagnosed 88% of patients (Accuracy: 88%, Sensitivity: 89%, Specificity: 88%, Positive Predictive Value: 93%, Negative Predictive Value: 82%) when combined with ERCP.

Importantly, tissue sampling (traditional biopsies) was inconclusive for a majority of patients (70 out of 112) while pCLE was inconclusive for only 16 patients, thus helping physicians to correctly identify the condition of 54 of the patients in this indeterminate group. Within this group, pCLE helped identify cancer earlier than traditional methods in 24 patients and correctly ruled out cancer in 30 patients with benign strictures.

The information provided by Cellvizio enabled endoscopists to improve patient care by avoiding unnecessary invasive and costly surgical procedures as well as repeat diagnostic procedures. Studies have shown that up to 50% of patients with indeterminate traditional biopsies undergo invasive bilio-pancreatic surgeries, reducing their long-term survival rates and creating significant unnecessary costs for the healthcare systems.

Sacha Loiseau, CEO and Founder of Mauna Kea Technologies, added: “These landmark clinical trial results provide strong additional validation of the benefits of using Cellvizio when performing interventional procedures in the biliary tree. With the Cellvizio technology, physicians are much more likely to get a confirmed diagnosis the first time, avoiding repeat procedures, delays and costs in providing appropriate treatment to patients suffering from bilio-pancreatic lesions such as pancreatic cysts and biliary strictures. With these additional results and recommendations, endomicroscopy with Cellvizio is rapidly becoming a must-have for interventional endoscopists performing these procedures.”



A video of Dr Slivka discussing the FOCUS results is available on the GIE journal website: [http://www.giejournal.org/content/video\\_interviews](http://www.giejournal.org/content/video_interviews)

**About biliary strictures and cholangiocarcinoma**

Biliary strictures is a condition affecting more than 50,000 people in the United States every year and can be linked to cholangiocarcinoma, an aggressive form of cancer. Although uncommon, this form of biliary cancer is devastating and notoriously difficult to diagnose using standard of care involving multimodality imaging exams and tissue sampling. Procedures involving tissue sampling in the area can create severe complications and have a low diagnostic sensitivity (<50%) for the detection of cholangiocarcinoma. As a result, many patients must undergo multiple procedures before reaching a definitive diagnosis, often resulting in inappropriate or delayed intervention.

**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 further information on Mauna Kea Technologies, visit [www.maunakeatech.com](http://www.maunakeatech.com)

**NewCap**

Europe – Investor Relations  
Florent Alba  
Tel: +33 (0) 1 44 71 94 94  
[maunakea@newcap.fr](mailto:maunakea@newcap.fr)

**Westwicke Partners**

US – Investor Relations  
Mark Klausner  
Tel : +1 (443) 213-0500  
[maunakea@westwicke.com](mailto:maunakea@westwicke.com)

**Berry & Company Public Relations**

US – Public Relations  
Bill Berry  
Tel: +1 212 253 8881  
[bberry@berrypr.com](mailto:bberry@berrypr.com)