## Largest Cellvizio Study To Date Demonstrates Near Perfect Correlation with Histology in Key GI Procedures

Cellvizio histologic correlation above 90% for Barrett's Esophagus, Biliary Strictures, and Pancreatic Cysts procedures

Presentation of data covering 399 cases from National French Registry announced in oral presentation at 2017 Annual French-speaking Meeting on Hepato-Gastroenterology and Digestive Oncology

Paris, France and Boston, MA, USA, April 3, 2017 - 5.45 PM CET - Mauna Kea Technologies (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, today announced the presentation of data from the National French Registry on Cellvizio® procedures confirming the strong performance of confocal laser endomicroscopy (CLE) in the diagnosis of major gastrointestinal diseases as compared to histological findings. The registry outcomes¹ were disclosed in an oral presentation during the Annual French-speaking Meeting on Hepato-Gastroenterology and Digestive Oncology on March 24, 2017 in Paris (JFHOD 2017).

The Cellvizio National French Registry is a post-market observational study sponsored by the French National Digestive Endoscopy Society (SFED). The presentation at JFHOD 2017 meeting covered data from 399 prospective CLE-procedures performed between September 2013 and February 2015 at 12 participating endoscopy centers. Overall imaging quality was ranked as good in 83% (331/399) of the cases, bad in only 1% (4/399) and correlation factor with histology (Kappa) was equal or greater than 0.90 in the following 3 key indications:

- **Barrett Esophagus Detection and Follow-up** (28% of the registry cases), Kappa was 0.90 for the differentiation of normal tissues, inflammatory, metaplasia and dysplastic lesions; Cellvizio allowed real time biopsy guidance or impacted immediate therapeutic decision in 84% of the patients
- **Biliary Strictures Characterization** (11% of the registry cases), Kappa was 0.94 for the differentiation of normal tissues, inflammatory, high-grade dysplastic lesions or carcinoma; Cellvizio allowed real time biopsy guidance or impacted immediate therapeutic decision in 90% of the patients
- Pancreatic cysts Characterization (30% of the registry cases), Kappa was 0.93 for the differentiation of serous cysts, mucinous cysts, IPMN, pseudocysts or neuroendocrine tumor; Cellvizio allowed real time diagnosis and impacted immediate therapeutic decision in 80% of the patients. More rare cases have been observed (lymph nodes, pancreatic masses, ampullomas ...) in 10% of the patients.

The remaining indications were gastritis follow-up in 5% of the patients, characterization of colorectal polyps in 11% and detection of dysplastic lesions in inflammatory bowel diseases in 5% with respective Kappa value of 0.78, 0.70 and 0.82.

One serious adverse event without consequence was reported but was not linked to the Cellvizio device.

Sacha Loiseau, Ph.D., Founder and Chief Executive Officer of Mauna Kea Technologies, commented, "We are proud to have supported the SFED in this endeavor. The results from this large, comprehensive and independent national registry confirm the expansion and ease of use of our technology, the quick adoption and learning curve, and the safety and the strong correlation of the Cellvizio procedure with histological and pathological findings. Cellvizio clearly allows gastroenterologists to make real-time therapeutic decision for improved patient management. The results from this registry will provide an important data point in our efforts to secure reimbursement for Cellvizio in France."

## Reference:

1. Online published abstract: http://www.snfge.org/content/resultats-de-lobservatoire-national-des-pratiq

## **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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