

## MAUNA KEA TECHNOLOGIES ANNOUNCES THAT THE FRENCH HIGH AUTHORITY FOR HEALTH HAS GIVEN A FAVORABLE OPINION FOR THE INSCRIPTION OF OPTICAL ENDOMICROSCOPY FOR BARRETT'S ESOPHAGUS ON THE LIST OF REIMBURSABLE PROCEDURES

- *This positive opinion follows a filling by the French Society of Digestive Endoscopy (SFED) in September 2010*

**PARIS, October 13<sup>th</sup>, 2014** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio<sup>®</sup>, the multidisciplinary optical biopsy platform, today announced that the Haute Autorité de Santé (HAS) - or French High Authority for Health, has delivered a favorable opinion for the inclusion of Cellvizio on the list of reimbursable procedures for use in patients with Barrett's Esophagus. Barrett's Esophagus is a pathology that must be closely monitored to detect if cancer of the esophagus has developed.

According to the HAS website, the opinion stipulates the following: "Given the evaluation presented in the technology evaluation report, the HAS is favorable to the inscription on the list of reimbursable procedures of optical endomicroscopy performed during the mapping of Barrett's Esophagus."

*"This favorable opinion is an important milestone for Cellvizio in our home market, where we design, develop and manufacture our products",* said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. *"Patients with Barrett's Esophagus, who require routine examinations given the risk of developing cancer, should at last benefit from improved monitoring and management thanks to optical biopsy."*

The HAS has also published its agenda for the period Q4 2014 – Q4 2015, during which it will evaluate the benefits of using optical endomicroscopy for the evaluation of Endoscopic Mucosal Resection scars in the colon during a colonoscopy and for the characterization of biliary strictures during a biliary endoscopy (ERCP) procedure.

**Next Press Release:** 2014 Q3 Sales on October 15<sup>th</sup>, 2014

### **About Barrett's Esophagus**

In most cases, Barrett's Esophagus is a complication of gastroesophageal reflux disease (GERD) in which the lower esophageal tissue lining gradually develops into abnormal tissue. Usually diagnosed around the age of 55-60, it affects 1% to 2% of the population, i.e. approximately 500,000 people in France. Barrett's Esophagus causes lesions that can become cancerous. The 5-year survival rate for patients who develop esophageal adenocarcinoma is less than 15%, but early detection improves survival.

Adenocarcinoma is a malignant tumor that begins in glandular (secretory) cells. Glandular cells are found in tissue that lines certain internal organs and makes and releases substances in the body, such as mucus, digestive juices, or other fluids. Most cancers of the breast, pancreas, lung, prostate, and colon are adenocarcinomas.

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



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