

## Cellvizio® Endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) as a Safe and Effective Diagnostic Tool

*Analysis by SAGES Technology and Value Assessment Committee concludes that Cellvizio® has an excellent safety profile and increases the diagnostic accuracy in a number of gastrointestinal pathologies*

Paris and Boston, May 26, 2020 – 6.00 PM CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe- and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced that the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee (TAVAC) published a review on the safety and efficacy of confocal laser endomicroscopy as a diagnostic tool for the evaluation of gastrointestinal pathologies. This article, entitled “SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy,” was published in a peer reviewed international journal, *Surgical Endoscopy* ([doi.org/10.1007/s00464-020-07607-3](https://doi.org/10.1007/s00464-020-07607-3)).

SAGES TAVAC publishes Technology Alerts on a monthly basis and longer safety and efficacy reviews on a periodic basis. The publication in *Surgical Endoscopy* was based on TAVAC’s systematic review of clinical studies on PubMed/Medline involving CLE in May 2018 as well as bibliographies of key references for relevant studies not available on PubMed. TAVAC’s objective was to evaluate the safety, value, and efficacy of CLE in the gastrointestinal tract. The results of TAVAC’s analysis concluded that CLE offers an excellent safety profile with rare adverse events related to the use of fluorescent agents. It has been shown to increase the detection of dysplastic Barrett’s esophagus, gastric intraepithelial neoplasia/early gastric cancer, and dysplasia associated with inflammatory bowel disease when compared to standard screening protocols. It also aids in the differentiation and classification of colorectal polyps, indeterminate biliary strictures, and pancreatic cystic lesions.

*“The process of the TAVAC review and experience of the Committee members show that Cellvizio has an excellent safety profile and clear clinical utility and efficacy as an adjunct to the standard of care across a range of gastrointestinal diseases and conditions,”* said Shawn Tsuda, MD, FACS, board-certified surgeon and Chair of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee (TAVAC). *“Early diagnosis and effective surveillance can have significant positive impacts on therapeutic management, and Cellvizio is an essential tool to improve diagnostic accuracy and reduce inappropriate interventions.”*

*“We are extremely pleased by SAGES’s endorsement of Confocal Laser Endomicroscopy in the diagnosis and surveillance of gastrointestinal diseases including GERD, Barrett’s Esophagus, and pancreatic cysts,”* said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. *“This peer reviewed analysis reinforces the position of Cellvizio® as an adjunct to the standard of care to effectively target biopsies and increase diagnostic yield, thereby improving patient outcomes and optimizing clinical costs through increased diagnostic accuracy.”*



In their analysis, the Committee outlined the high diagnostic accuracy of CLE as an advanced imaging adjunct across all gastrointestinal endoscopic indications compared to current standard of care. They also highlighted the improvement of diagnostic yield for specific indications such as chronic GERD, Barrett's Esophagus, early gastric cancer, gastric intestinal neoplasia, and pancreatic cystic lesions, as well as the effectiveness for evaluation and ongoing surveillance of inflammatory bowel disease (IBD).

One important consideration for endorsement of a new technology for gastrointestinal disease diagnosis is its potential for reducing inappropriate or unnecessary therapy for non-neoplastic conditions, therefore improving overall procedure-related complications, optimizing surveillance intervals, reducing unnecessary interventions, and limiting histological analysis of insignificant lesions while detecting early dysplasia to improve patient outcomes.

#### **About SAGES**

SAGES (The Society of American Gastrointestinal and Endoscopic Surgeons) was founded in 1981 to foster, promote, support and encourage academic, clinical and research achievement in gastrointestinal endoscopic surgery. SAGES currently boast more than 6,500 general surgeon members from countries all around the world. SAGES annual meeting is oriented toward minimally invasive surgery and in 2018 had an attendance of over 2,700 surgeons.

#### **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/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, and China. For more information on Mauna Kea Technologies, visit [www.maunakeatech.com](http://www.maunakeatech.com)

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