# Mauna Kea Technologies Announces First Published Report of Live "Tele-Cellvizio®" Utilization *In Vivo* between Surgeons and Remote Pathologists

Results of breakthrough PERSEE trial involving live transmission and robotized use of Cellvizio confocal miniprobe published online in *Surgical Endoscopy* 

Paris and Boston, October 2, 2018 – 5:35 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 new results from the PERSEE study examining the use of Cellvizio during digestive surgery with live remote transmission to pathologist were published this month in *Surgical Endoscopy*, the official journal of SAGES (Society of American Gastrointestinal and Endoscopic Surgeons).

This scientific <u>publication</u>, entitled "Intraoperative confocal laser endomicroscopy for real-time in vivo tissue characterization during surgical procedures", reports on outcomes of 21 consecutive patients that underwent laparoscopic surgery at the Institut Mutualiste Montsouris (IMM) in Paris, France, between 2014 and 2015. Endomicroscopic images were acquired using a robotized Confocal Miniprobe™, connected to a Cellvizio endomicroscopy system that allowed near-infrared illumination (at a wavelength of 785 nm). A live audiovisual transmission was established between the surgeon and the pathologist for real-time interpretation of optical biopsies, or Tele-Cellvizio®. Intraoperative pCLE performance for the diagnosis of suspicious nodules was assessed using corresponding surgical histopathology as reference standard.

A previous study defined specific pCLE criteria based on *ex vivo* benign and malignant peritoneal and hepatic nodules exhibited a very high pCLE diagnostic accuracy of 93% for both the surgeon and the pathologist [1,2]. This new study confirms that the criteria identified *ex vivo* are well reproduced *in vivo* [3]. pCLE clearly allowed the differentiation of inflammatory from malignant tissues when the cancerous cells reached the peritoneal and hepatic nodule surface. pCLE sensitivities and specificities were 67% and 100%, and 38% and 100% for peritoneal and hepatic nodules, respectively.

"These results add to the growing evidence that the Cellvizio platform can help surgeons make appropriate real-time decisions and eliminate uncertainties during procedures," said Brice Gayet, Professor of Digestive Surgery at Institut Mutualiste Montsouris. "Real-time intraoperative pCLE with near-infrared illumination provides additional information in terms of tissue characterization, and, in combination with tele-in vivo-pathology, allows interactive collaboration between the surgeon and the pathologist during surgical procedures."

Sacha Loiseau, Ph.D., Founder and Chief Executive Officer of Mauna Kea Technologies, added, "The interweaving of Cellvizio technologies with robotics, Al and digital multiplex transmission has been integral to our product roadmap for many years. These results from the PERSEE study represent one of many milestones passed already on this roadmap, as we make Cellvizio technologies more and more compatible with existing and novel surgical platforms. The body of clinical evidence showing that Cellvizio can add significant value in cancer surgeries, by bringing the same proven accuracy level in tissue characterization obtained in other indications and helping confirm surgical margins in real-time, is growing rapidly and we look forward to exciting new results."

# **About the PERSEE project**

The PERSEE project was awarded 7.6 million euros in April 2010 from OSEO (now BpiFrance) in order to develop a robotized, miniature, flexible endomicroscope for the minimally invasive exploration of the abdominal cavity. Mauna Kea Technologies is the leader of this collaborative project along with EndoControl,

a developer of robotic solutions to assist surgeons and physicians, the Institut des Systèmes Intelligents et de Robotique (ISIR) at the Université Pierre et Marie Curie, the digestive diseases department of the Institut Mutualiste Montsouris (IMM) and the departments of Cellular Imaging, Gastroenterology and Pathobiology of the Institut de Cancérologie Gustave Roussy (IGR).

- [1] Angelo Pierangelo, Pierre Validire, Ali Benali, David Fuks and Brice Gayet "Diagnostic accuracy of confocal laser endomicroscopy for the characterization of liver nodules", European Journal of Gastroenterology & Hepatology, 2016.
- [2] Angelo Pierangelo, David Fuks, Ali Benali, Pierre Validire and Brice Gayet "Diagnostic accuracy of confocal laser endomicroscopy for the ex vivo characterization of peritoneal nodules during laparoscopic surgery", Surgical Endoscopy, 2016.
- [3] David Fuks, Angelo Pierangelo, Pierre Validire, Marine Lefevre, Ali Benali, Guillaume Trebuchet, Aline Criton, Brice Gayet "Intraoperative confocal laser endomicroscopy for real-time in vivo tissue characterization during surgical procedures". Surgical Endoscopy, 2018.

#### **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, South Korea, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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