Mauna Kea Technologies announces that its CONTACT 2 pivotal trial in pancreatic cysts has met primary and secondary endpoints demonstrating Cellvizio's significantly higher diagnostic performance compared to the current standard of care

Results from large, prospective, multi-center CONTACT 2 study published in Endoscopy, the official Journal of the European Society of Gastrointestinal Endoscopy

Cellvizio enabled a conclusive and correct diagnosis on 21 of 23 patients who had undergone an inconclusive endoscopic ultrasound procedure with fine needle aspiration

Paris and Boston, November 6, 2018 – 5:45 pm CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe-based and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced results from the large, prospective, multi-center validation CONTACT 2 study that met its primary and secondary endpoints, demonstrating significantly higher diagnostic performance of nCLE with Cellvizio® compared to standard of care methods in patients with pancreatic cyst lesions (PCLs). The findings were published in the article "Needle-based confocal laser endomicroscopy of pancreatic cystic lesions: a prospective multicenter validation study in patients with definite diagnosis" in the peer-reviewed publication *Endoscopy*.

Bertrand Napoleon, M.D., Department of Gastroenterology at the Jean Mermoz Private Hospital in Lyon, France and first author of the study, commented, "Current methods of EUS and CEA have limited diagnostic yield and accuracy and are often associated with unnecessary repeated follow-up procedures or surgery, which have important consequences both for patients and healthcare systems. Our study demonstrated very high sensitivity and specificity of nCLE criteria for accurately diagnosing single, non-communicating, pancreatic cystic tumors, concluding that the routine addition of nCLE to standard EUS-FNA procedures has the potential to positively impact patient management and provides significant economic benefits for patients and hospitals. We look forward to providing further results on Cellvizio's patient management impact in the near future."

Robert L. Gershon, CEO of Mauna Kea Technologies, said, "The results of this large prospective clinical trial illustrate our mission to eliminate diagnostic and treatment uncertainties for healthcare teams and patients. This study reinforces the growing body of evidence on the clinical advantages of Cellvizio in pancreatic cystic lesions to improve diagnostic yield and accuracy. We have now clearly demonstrated that Cellvizio surpasses the existing standard of care and is improving outcomes for patients while maintaining safety".

The CONTACT 2 study enrolled 217 patients at five centers in France to evaluate Cellvizio diagnostic performance using surgical histopathology or endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) cytohistopathology as the gold standard. Of eligible participants, 206 patients underwent Cellvizio on single, noncommunicating PCLs as incidentally identified by CT or MRI scans.

Results exceed the previously reported performance of Cellvizio in PCLs, key results include:

- Cellvizio nCLE was the most efficient method for determining the diagnosis of PCLs compared to CEA and EUS.
- Sensitivities and specificities of Cellvizio for the diagnosis of serous cystadenoma, mucinous PCL, and premalignant PCL were all greater than 95%.
- Perfect specificities (100%) were confirmed for benign serous cystadenomas and for the overall group of mucinous lesions.

- 1.3 percent of patients suffered from acute pancreatitis which is similar to standard EUS-FNA procedures.
- The mean Cellvizio procedure duration was decreased, likely due to the learning curve.
- In a subgroup of 23 patients who had undergone an inconclusive EUS-FNA procedure in the past, Cellvizio was conclusive in 91% of patients (21 of 23) and established a correct diagnosis in 100% of them (21 of 21).
- 4.5% of patients with confirmed serous cystadenomas (1 of 22) underwent surgical resection due to diagnostic uncertainty, compared to the 36% on average who undergo this unnecessary resection due to diagnostic uncertainty; confirming the cost-effectiveness of Cellvizio.

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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