

PHYSICIANS USING OPTICAL BIOPSY WITH CELLVIZIO DISCOVER A NEW DIAGNOSTIC CRITERION SPECIFIC FOR BENIGN PANCREATIC CYSTS AND INVISIBLE WITH OTHER IMAGING TECHNOLOGIES

- *Mauna Kea Technologies' study shows that needle-based confocal laser endomicroscopy with Cellvizio confirms nature of benign serous cystadenomas with high specificity.*
- *Findings from prospective multicenter CONTACT 1 study published in peer-reviewed journal Endoscopy.*

Paris, France, October 21, 2014 - Mauna Kea Technologies (Euronext : MKEA FR0010609263), inventor of Cellvizio, the multidisciplinary optical biopsy platform, today announced results from a prospective multicenter study showing that optical biopsy procedures performed with Cellvizio successfully confirmed the presence of benign pancreatic cysts in 100% of patients where a superficial vascular network was observed. Results of the study were published today in the peer reviewed journal *Endoscopy* in an article entitled: "A novel approach to the diagnosis of pancreatic serous cystadenoma: needle-based confocal laser endomicroscopy".

The study known as CONTACT 1 (listed on clinicaltrials.gov under NCT01563133) included 31 patients and focused on the differential diagnosis of solitary pancreatic cystic lesions using needle-based confocal laser endomicroscopy (nCLE). The study had a specific emphasis on diagnosis of serous cystadenomas, a benign form of pancreatic cysts.

Among patients in the study, the presence of a specific superficial vascular network was identified and shown to be 69% sensitive and 100% specific for benign serous cystadenomas (SCA). Using specific markers, the presence of a diffuse and homogeneous capillary network was confirmed by expert pathologists in this type of lesions. In the 69% of patients with benign cysts where this vascular network was observed using the Cellvizio endomicroscopy technology, fully 100% were confirmed to have benign cysts.

This specific characteristic has not previously been identified by other imaging modalities and constitutes a major step forward in the diagnosis of serous cystadenoma.

"Our now extensive experience with nCLE has convinced us that observation of this previously invisible vascular network is highly specific for the diagnosis of SCA," said Dr Bertrand Napoléon, chief of endoscopy at Hôpital Privé Jean Mermoz in Lyon and principal investigator of the study. "The ability to visualize this network with Cellvizio means we can now consider this as a criterion for diagnosis with the potential to avoid unnecessary surgeries or follow-up procedures for many patients."

The accuracy, sensitivity, specificity, positive predictive value, and negative predictive value of this sign for the diagnosis of SCA were 87%, 69%, 100%, 100% and 82%, respectively.

In addition to publication of data in *Endoscopy*, Cellvizio was also featured prominently at three of the leading global gastroenterology congresses in recent weeks, including United European Gastroenterology Week (UEGW) in Vienna, Austria, the annual congress of the American College of Gastroenterology (ACG) in Philadelphia, United States, and the Japan Digestive Disease Week (JDDW) in Kobe, Japan.

"The results from our landmark CONTACT 1 study together with our expanded presence for Cellvizio at three leading global meetings in gastroenterology in recent weeks reinforce the expanding interest in the advantages of our optical biopsy technology. We look forward to sharing results from additional clinical research involving Cellvizio in the months ahead in our efforts to bring this technology to more clinicians who need improved imaging capabilities," said Sacha Loiseau, CEO and founder of Mauna Kea Technologies.

At the UEGW meeting more than 40 research studies were presented involving the use of Cellvizio for the characterization of GI lesions and patient management optimization. Ten separate presentations reported how Cellvizio could improve patient care by offering a new alternative to pancreatic cyst characterization based on in vivo imaging of cystic lesions possible with the AQ-Flex probe. This was perfectly illustrated by a live case performed by Pr. Kenneth Chang. Among more than 12 presentations about Cellvizio at the ACG meeting, results from a study reporting the performance of Cellvizio for the characterization of colorectal lesions was granted a special presidential award. At JDDW researchers from throughout Asia presented findings on the latest advances in the use of confocal laser endomicroscopy in management of GI diseases.

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®, a probe needlebased Confocal Laser Endomicroscopy (pCLE/nCLE) 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 virtually any endoscope. 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 has also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For further information on Mauna Kea Technologies, visit www.maunakeatech.com

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