New Data on Cellvizio Presented at DDW 2013 Suggests That Optical Biopsies May Help Confirm and Rule Out Pancreatic Cystic Tumors*

The Associated Press

Mauna Kea Technologies (NYSE Euronext: MKEA), leader in the optical biopsy market and developer of Cellvizio®, the fastest way to see cancer, today announced that optical biopsies using a microscope so tiny it fits through a small needle show clear cellular-level images inside pancreatic cysts, which could assist physicians in the diagnosis of pancreatic cystic tumors and help patients with benign cysts avoid unnecessary surgery, according to new data presented at Digestive Disease Week 2013, which concludes here today.

"With current imaging and sampling techniques, it remains difficult to accurately rule out malignant or pre-malignant pancreatic cystic tumors, so certain patients have to undergo surgery before a diagnosis can be confirmed," said Marc Giovannini, MD, Head of the Endoscopy Unit at Paoli-Calmettes Institute in Marseille, France. "This can have dramatic implications for these patients, especially when we find out the cyst was benign. This new data shows that needle-based optical biopsies may provide the missing information needed to separate high-risk and low-risk cysts. In my practice, I already see a significant impact on the management of patients with pancreatic cysts."

Based on images from the CONTACT 1 study led by Bertrand Napoleon, MD, from the Hôpital Jean Mermoz in Lyon, France and colleagues were able to identify superficial vascular networking (SVN) as a key feature of a specific sub-type of pancreatic cyst (serous cystadenoma) that is always considered to be benign. According to their analysis(i) (Abstract Tu1226) of 18 patients with pancreatic cysts larger than 2cm, needle-based optical biopsies generated specificity and positive predictive value of 100% in identifying SVN. They also found that optical biopsy images are easy to interpret with these criteria and that after limited training, both novice and expert endoscopists can agree on a diagnosis based on the images.

"Real time optical biopsies have helped us identify a key feature of this kind of benign cyst," Dr. Napoleon said. "With this new information, we should be able to help patients with serous cystadenomas avoid unnecessary surgery. We look forward to prospectively validating these results and believe this new information could have a significant impact on patient care."

"We have dedicated ourselves to bringing microscopic imaging into parts of the body where it was never feasible before so patients can receive diagnoses faster -- and get the right treatment," said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. "We're very proud of the innovation behind the AQ-Flex miniprobe and of the results presented at DDW 2013. We look forward to continuing to work with experts around the globe to confirm these exciting results."

In April, the U.S. Food and Drug Administration (FDA) cleared the AQ-Flex 19 miniprobe to provide real-time optical biopsies during endoscopic ultrasound-guided fine needle aspiration (EUSFNA) procedures in the digestive tract. The miniprobe had been commercially available in Europe since mid-2012 and in select additional countries around the world.

(*) Disclaimer: These statements and the associated reference to specific clinical studies, are not intended to represent claims of safety or effectiveness for detecting or treating any specific condition or disease state. Rather this information is intended to provide useful reference to selected published literature describing physician experiences with the associated clinical uses. These statements have not been reviewed, cleared, or approved by the U.S. FDA.

Any diagnostic assessment should always be made by the attending physician, based on the evaluation of all sources of clinical, endoscopic and other relevant information.

About Digestive Disease Week® (DDW®)
DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18 - 21, 2013, at the Orange County Convention Center, Orlando, FL. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About Mauna Kea Technologies
Mauna Kea Technologies is a global medical device company dedicated to the advent of optical biopsy. The company researches, develops and markets innovative tools to visualize and detect cellular abnormalities during endoscopic procedures. Its flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers high-resolution cellular views of tissue inside the body. Large, international, multicenter clinical trials have demonstrated Cellvizio's ability to help physicians more accurately detect early forms of disease and make treatment decisions immediately. Designed to improve patient outcomes and reduce costs within a hospital, Cellvizio can be used with almost any endoscope. Cellvizio has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use in the GI tract, biliary and pancreatic ducts and lungs and during fine needle aspiration procedures.

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

(i) Napoleon, MD, Bertrand, "In Vivo Characterization of Pancreatic Serous Cystadenomas by Needle-Based Confocal LASER Endomicrosopy (nCLE). Intra and

Inter Observer Agreement - Contact Study," DDW 2013, Orlando, Abstract Tu1226

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