

Cellvizio's *in Vivo* Microscopic Images Depict Easily-Recognizable Features of Malignant and Benign Tissues in Bile and Pancreatic Ducts

Preliminary Data from International, Multi-Centric Registry Presented During an Oral Presentation at GASTRO 2009

LONDON (November 23, 2009) – Clinical investigators have defined a series of descriptive criteria which may improve how physicians interpret confocal microscopic images of tissue inside the bile and pancreatic ducts with Cellvizio®, the world's smallest microscope. These findings are a result of the preliminary results of a multi-centric international registry study presented today during an oral presentation at the GASTRO 2009 conference, taking place in London, England from November 21-25. The investigators are currently evaluating those unique features on the larger set of data from the study to determine the predictive value of the criteria in determining malignancy.

“The tiny Cellvizio mini-probe easily fits into narrowing bile and pancreatic ducts and offers us clear, reproducible microscopic images with definable features of this suspicious tissue for the first time,” said lead investigator Yang Chen, MD, FACP, FACG, Clinical Practice Director of the Division of Gastroenterology and Director of Endoscopy, the University of Colorado Hospital, Aurora, Colorado. “Once the full data analysis is complete, we will have a much greater understanding of how to properly interpret these *in vivo* microscopic images, so we can differentiate malignant from benign tissues in real time. Ultimately, we believe this new imaging tool will help us identify and treat patients with pancreaticobiliary disease more quickly and effectively, which is crucial given how fast pancreatic and bile duct cancers advance.”

Tissue sampling techniques traditionally used to diagnose pancreatic or bile duct cancer are associated with low sensitivity, around 50 percent, which means nearly one out of two cancers are missed in this difficult to image area.

The Cellvizio ERCP registry study was a longitudinal registry of patients undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP) imaging procedures to investigate whether their bile and/or pancreatic ducts had narrowed into strictures because of cancer or inflammation. In this study, the Cellvizio mini-probe was used along with the ERCP procedure to offer physicians a microscopic-level view of the tissue lining these ducts so they could identify and document suspicious lesions, rather than take random tissue samples. A follow-up period of one year was included in the study to confirm negative findings.

In this preliminary analysis, 77 patients with indeterminate strictures in their bile or pancreatic ducts underwent an evaluation with the Cellvizio system during ERCP. Physicians were able to insert the mini-probe through a catheter or a cholangiopancreatoscope (CP) in all 77 patients. At the time of this presentation, 42 of the patients either had tissue confirmed malignant or had undergone a follow-up exam showing benign tissue more than three months after the initial procedure.

“We are encouraged by these interim results as we believe Cellvizio® is aiding physicians in identifying the cause of the stricture that is seen in the bile duct, and the interpretation criteria presented should help in documenting their diagnosis,” said Sacha Loiseau, Founder, President and CEO of Mauna Kea Technologies. “We are committed to realizing Cellvizio’s potential in ERCP clinical practice through our efforts to offer physicians an effective tool that complements current practice and that may improve how they diagnose and determine treatment for pancreaticobiliary and other gastrointestinal diseases.”

Three additional United States (US) sites (Beth Israel Deaconess Medical Center, Boston; New York Presbyterian Hospital/Columbia University Medical Center, New York; University of Pittsburgh Medical Center, Pittsburgh) and two European sites (Klinikum rechts der Isar, Munich, Germany; Institut Paoli-Calmettes, France) are participating in the study, which ultimately enrolled 130 patients. Enrollment closed in early October, but follow up continues in the study and full results will be announced at a later date. This study was conducted under local IRB approval at each participating center, and each patient included in the study provided adequate informed consent.

About Pancreatic Cancer:

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. Depending on the extent of the cancer at the time of diagnosis, the prognosis is generally regarded as poor; less than 5 percent of those diagnosed are still alive five years after diagnosis. Estimated new cases and deaths from pancreatic cancer in the US in 2009:

New cases: 42,470; Deaths: 35,240. In the United Kingdom (UK), pancreatic cancer is the fifth most common cause of cancer death. In 2007, more than 7,700 people in the UK died from pancreatic cancer. Worldwide, more than 230,000 people were diagnosed with pancreatic cancer in 2002, that latest year that worldwide statistics are available.

About Cholangiocarcinoma:

Cholangiocarcinoma is a cancer of the bile ducts, which drain bile from the liver into the small intestine. Cholangiocarcinoma has an annual incidence of 1–2 cases per 100,000 in the Western world, but rates of cholangiocarcinoma have been rising worldwide over the past several decades.

About Mauna Kea Technologies and Cellvizio:

Mauna Kea Technologies believes that in continuously pushing the limits of observation of life and by helping physicians design new medical references and guidelines, it can improve patient care and reduce healthcare costs. Its flagship product, Cellvizio®, is the world's smallest and most flexible microscope and the first system designed to provide live, real-time images of internal human tissues at the cellular level during endoscopic procedures. This new, advanced imaging technique helps physicians more effectively assess the tissues of interest and differentiate normal versus abnormal tissues that may be indicative of cancer, so patients potentially can be treated earlier and may undergo fewer biopsies. Physicians and thought leaders at more than 60 top medical institutions around the world have completed over 3,000

of these procedures and have published more than 25 peer-reviewed papers on the technology in medical journals. Cellvizio has premarket notification 510(k) clearance from the United States Food and Drug Administration and the European CE-Mark for use in the gastrointestinal and pulmonary tracts. For more information visit www.maunakeatech.com.

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