



Cellvizio Announces That University Of Colorado Physicians Treat First U.S. Patients In Large Study To Confirm If Live, Microscopic Imaging Enhances A Physician’s Ability To Differentiate Cancerous Lesions In The Bile And Pancreatic Ducts

Fort Washington, PA. (January 08, 2009) – Doctors at the University of Colorado Hospital in Aurora have treated the first patients in a study to confirm whether using Cellvizio®, the world’s smallest microscope, with a standard diagnostic procedure will help physicians identify and differentiate pre-cancerous and cancerous lesions in the bile and pancreatic ducts more effectively than the standard method alone.

"A growing body of clinical evidence suggests that adding this non-invasive microscopic tool to the standard bile and pancreatic duct diagnostic procedure increases our ability to accurately locate – and then remove – malignant lesions," said Yang K. Chen, MD, FASGE, FACG, Clinical Practice Director of the Division of Gastroenterology and Director of Endoscopy the University of Colorado Hospital, and Lead Investigator for this study. "We hope that this large registry study will confirm those findings and offer a new, more effective way to diagnose diseased tissue from these difficult-to-reach-areas."

Up to 200 patients will be enrolled in the study, which is also expected to take place at three additional U.S. sites and one center in Germany. To qualify, the patients must be planning to undergo the standard biliary or pancreatic duct diagnostic procedure, known as endoscopic retrograde cholangiopancreatography (ERCP), because their doctor suspects that they have a lesion or blockage in either of the ducts.

The study data will measure endoscopists’ ability to correctly identify cancerous and pre-cancerous tissue and to correctly differentiate the healthy tissue using ERCP alone and together with the Cellvizio probe-based confocal laser endomicroscope. These presumptive diagnoses will be compared against a confirmed histopathologic endpoint with up to 12 month follow up. Study physicians will also measure various safety and technical performance parameters.

U.S. sites also expected to participate include Beth Israel Deaconess Medical Center in Boston; New York Presbyterian Hospital/Columbia University Medical Center in New York; and the University of Pittsburgh Medical Center in Pittsburgh. European sites include Klinikum rechts der Isar in Munich, Germany.

Details of the study can be found on www.clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT00779688).

This study is sponsored by Mauna Kea Technologies/Cellvizio Inc.

About Cholangiocarcinoma



Cholangiocarcinoma is a cancer of the bile ducts, which drain bile from the liver into the small intestine. With an annual incidence rate of one to two cases per 100,000 in the Western world, this disease has been steadily increasing over the past several decades. Risk factors include inflammation of the bile ducts and liver malfunctions. Symptoms include jaundice, weight loss and generalized itching. This disease is diagnosed through a combination of blood tests, imaging, endoscopy and sometimes surgical exploration. To date, surgery is the only potentially curative treatment.

About Cellvizio(r)

Cellvizio(r), the world's smallest microscope, is the first system designed to provide live images of internal human tissues at the cellular level during endoscopic procedures. This new method, known as probe-based confocal laser endomicroscopy (pCLE), allows physicians to pinpoint and remove diseased tissue with endoscopic tools on the spot, or, in more serious cases, send the patient directly to surgery. This new, advanced imaging technique helps physicians more effectively detect cancer so patients can be treated earlier and undergo fewer biopsies. Physicians and thought leaders at more than 40 top medical institutions around the world have completed over 2,000 of these procedures and have published more than 25 peer-reviewed papers on the technology in major medical journals. Cellvizio, which delivers up to 12 images per second and can be used with almost any endoscope, has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use in the gastrointestinal and pulmonary tracts.

About Mauna Kea Technologies/Cellvizio Inc.

Mauna Kea Technologies, which operates as Cellvizio Inc. in the U.S., is a venture-backed medical device company based in Paris, France, with U.S. offices in Fort Washington, Penn. With its flagship Cellvizio(r) system, the company leads the growing in vivo cellular imaging market, enabling physicians to visualize, diagnose and treat pathologies that cannot be seen using other imaging techniques. Investors include Psilos Group, Seventure and Credev. For more information about Mauna Kea Technologies: www.maunakeatech.com

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