Cellvizio®

Cellvizio® Shown To Improve Biopsy Targeting in Barrett's Esophagus

New Data on World's Smallest Microscope Published in GUT Journal

PARIS (December 11, 2008) – New data show that real-time, *in vivo* imaging with Cellvizio®, the world's smallest microscope, helps physicians target esophageal biopsies more effectively than traditional methods, improving their ability to determine if Barrett's esophagus has become pre-cancerous, according to a study published in the December issue of *GUT*, the International Journal of Gastroenterology and Hepatology (Gut. 2008 Dec.; 57 (12): 1648-53).

"Using images from this tiny microscope, we were able to show that a physician who is trained to use the Cellvizio device may identify the normal tissue fairly accurately," said Heiko Pohl, MD, of the Dartmouth-Hitchcock Medical Center and lead author of the study. "Traditional endoscopic cameras don't differentiate cancerous or precancerous Barrett's tissue, so we take random samples from sections of the region in hopes that it represents an accurate sampling. A more precise, real-time, microscopic imaging device will help us more accurately target dangerous Barrett's tissue and remove or treat it immediately before it develops into esophageal cancer." Drs. Alexander Meining, Klinikum rechts der Isar in Munich, Germany and Thomas Rösch, Charité University Hospitals in Berlin, Germany contributed to the study's findings as well.

Two independent examiners evaluated 199 and 200 biopsy sites in a multi-centric study, respectively. Their blinded diagnostic assessments matched in 176 cases. Of those 176 biopsy sites, the physicians came to an accurate diagnosis 93.3% of the time. They accurately determined which patients had pre-cancerous tissue 80% of the time and correctly differentiated the non-cancerous tissue 94.1% of the time. Of the lesions which tested negative, the physicians were 98.8% accurate (negative predictive value).

Barrett's esophagus occurs when gastroesophagul reflux disease (GERD) causes stomach acid to leak back into the esophagus and damage the lining. This can increase the risk of cancer of the esophagus (adenocarcinoma), the symptoms of which can be difficulty swallowing or weight loss. Since the 1980s, incidence rates of adenocarcinoma of esophagus (ACE) have been increasing in both genders in developed countries. ACE is the fastest rising malignancy among white men in the United States, with a relative increase even higher than that observed for breast cancer, malignant melanoma, or prostate cancer. From 1975 to 2001, the incidence of ACE increased sixfold in the United States, from 4 to 23 cases per million (Journal of the National Cancer Institute 2005;97:142-146).

About Cellvizio®

Cellvizio®, 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® 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 Creadev. For more information about Mauna Kea Technologies: www.maunakeatech.com

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