



First ever report of Cellvizio® use in cystoscopy

New Data on World's Smallest Microscope Presented at American Urology Association (AUA) Annual Meeting

PARIS (April 27th, 2009) – New data show that real-time, *in vivo* imaging with Cellvizio®, the world's smallest microscope, can be used in the urology field and may help urologists to differentiate low and high-grade bladder tumors from normal bladder tissue, according to data presented today at the American Urological Association's (AUA) Annual meeting being held in Chicago from April 25th to 30th. Cellvizio probe-based confocal laser endomicroscopy (pCLE) provides live images of internal human tissues at the cellular level during examination procedures enabling faster clinical decision making.

“With additional clinical investigation and further technological innovation, pCLE could provide a useful adjunct to white light cystoscopy in bladder cancer diagnosis and streamline patient management,” says Joseph Liao, Assistant Professor of Urology at Stanford University and Chief of Urology at Veterans Affairs Palo Alto Health Care System, who led the investigation. “Adding pCLE may potentially improve the yield of bladder biopsy in some patients while avoiding unnecessary biopsy in others.”

This study on 27 patients represents the first *in vivo* microscopic evaluation of the human bladder using pCLE and demonstrates that healthy and cancerous tissue may be differentiated in real time. The study found that normal urothelium was characterized by a network of regular polygonal-shaped cells, with superficial umbrella cells larger than deeper intermediate cells, while high-grade tumors had much more architectural irregularity and cellular pleomorphism.

“This study shows real promise for the introduction of pCLE in the field of urology,” said Sacha Loiseau, Founder, President and CEO of Mauna Kea Technologies. “These findings demonstrate Cellvizio's potential to impact how physicians diagnose and treat cancer and diseases in the urinary tract, just as we've seen in the gastrointestinal tract and lungs”

The study, titled “Optical Biopsy of Human Bladder Neoplasia with In Vivo Confocal Laser Endomicroscopy,” was conducted under an institutional review board (IRB)-approved protocol and is registered on [clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT: 00801762, <http://www.clinicaltrials.gov/ct2/show/NCT00801762>)

Bladder cancer is one of the most commonly diagnosed cancers (4th in men and 8th in women), with more than 60,000 new cases per year in the United States, which makes it more prevalent than lung cancer. Current standard for the diagnosis of bladder cancer is cystoscopy, which involves the insertion of an endoscope through the urethra into the bladder. Excisional biopsy of the bladder tumor is required to establish the stage: that is, to differentiate whether the tumor is superficial or muscle-invasive. Muscle-invasive bladder cancer requires removal of the bladder (radical cystectomy). Superficial bladder



cancer is usually amenable for endoscopic resection (transurethral resection of bladder tumor, or TURBT), but there is a 50-90% chance of recurrence. The need for lifelong surveillance makes bladder cancer the most expensive cancer to treat from the time of diagnosis to death.

“There is a significant need for more sensitive and specific, less invasive, and cost effective diagnostic modality for bladder cancer,” Dr. Liao said. “There is considerable interest in the urologic community to improve the diagnostic accuracy of white light cystoscopy, as evidenced by interests in imaging modalities such as fluorescence cystoscopy and optical coherence tomography. However, significant hurdles remain regarding the diagnostic specificity and the image resolution of these novel techniques. pCLE is an optical imaging modality that may bridge the shortcomings of the other imaging modalities and provide an important clinical utility for *in vivo* diagnostics.”

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 50 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 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

Mauna Kea Technologies, a French company with a multi-disciplinary scientific approach, has developed Cellvizio, a probe-based Confocal Laser Endomicroscopy (pCLE) system that makes dynamic imaging of life at the cellular level a reality. The cellvizio.net scientific knowledge interactive database is enabling an international community of leading scientists and physicians to share their ground-breaking work based on Cellvizio in gastroenterology and various fields of science and medicine. Mauna Kea Technologies is backed by leading life science investors, which include Psilos Group, Seventure and Credev. For more information about Mauna Kea Technologies, visit www.maunakeatech.com.

Mauna Kea Technologies Media Contact:

Erich Sandoval of Lazar Partners

Phone: 917-497-2867

E-mail: esandoval@lazarpartners.com