



## **Cellvizio Helps Urologists Differentiate Cells in the Bladder in Real Time**

### ***First Study of Probe-Based Confocal Laser Endomicroscopy (pCLE) in the Bladder Published in The Journal of Urology***

PARIS (October 5, 2009) – Urologic surgeons from Stanford University reported that Cellvizio® has been used to differentiate benign inflammation in bladder tissue from cancerous tissue in real time. Cellvizio®, the world’s smallest flexible microscope, was used during routine cystoscopy examinations to produce the findings, according to a study published in the October issue of *The Journal of Urology*, where it was also featured on the cover.

“Patients suspected to have bladder cancer are diagnosed and treated with cystoscopy and transurethral resection. In patients with superficial bladder cancer, lifelong surveillance is required due to the high recurrence rate associated with the disease,” said Joseph C. Liao, M.D., Assistant Professor of Urology at Stanford and Chief of Urology at the Veterans Affairs Palo Alto Health Care System, where the 27-patient pilot study was conducted. “An optical biopsy tool that can help us differentiate and grade cancerous lesions from benign inflammation in real time will be a significant advance over standard white light cystoscopy. It will likely lead to improved clinical decision making and planning of invasive surgical procedures. We look forward to investigating this technology further.”

Patient enrollment in a larger study of the pCLE system from Mauna Kea Technologies is expected to commence shortly. The Cellvizio system will be used during rigid and flexible cystoscopy procedures to confirm whether physicians can differentiate between tissue inflammation and neoplasia when viewing its live microscopic images of bladder tissue.

“These findings demonstrate Cellvizio’s potential to impact how physicians diagnose and treat cancer and diseases in the urinary tract,” said Sacha Loiseau, Founder, President and CEO of Mauna Kea Technologies. “We intend to continue our clinical efforts to broaden our understanding of how our technology can answer unmet needs and improve patient care within the urology, gastroenterology and pulmonology fields.”

Top-line data from the recently-published study were presented at the American Urological Association’s Annual meeting, held in Chicago this past April.

Bladder cancer is one of the most commonly diagnosed cancers (4<sup>th</sup> in men and 8<sup>th</sup> in women), with more than 60,000 new cases per year diagnosed in the United States alone, 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 (TURBT), but there is a 50-90% chance of recurrence. Therefore, once a patient is diagnosed they are reassessed at frequent intervals for the remainder of their lives. It is this need for lifelong surveillance, which makes bladder cancer the most expensive cancer to manage and treat from the time of diagnosis to death.

**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](http://www.maunakeatech.com).

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