



MAUNA KEA TECHNOLOGIES RECEIVES 510(k) REGULATORY CLEARANCE FROM U.S. FDA FOR CELLVIZIO IN UROLOGY

- *Clearance in urology expands potential applications of Cellvizio beyond GI and pulmonary applications*
- *Company makes further progress in positioning optical biopsy technology for new global market opportunities*

PARIS, March 5, 2014 – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), leader in the optical biopsy market, announced today it has obtained a 510(k) regulatory clearance from the U.S. Food & Drug Administration (FDA) for Cellvizio in the field of urology. The clearance covers the use of, Cellvizio's Uroflex™ B and CystoFlex™ F Confocal Miniprobes within anatomical tracts including but not limited to urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

This new clearance positions Mauna Kea's Cellvizio optical biopsy technology for use in a range of urology applications including bladder imaging during cystoscopy as well as the ureters, where traditional biopsies are very difficult to perform and have poor yield.

"This important approval is based on years of clinical research that has demonstrated the benefits of Cellvizio in a range of urological indications," said Dr Joseph Liao, Associate Professor of Urology, Stanford University and Chief of Urology at the Veterans Affairs Hospital in Palo Alto, adding, "This technology offers urologists an exciting new window to visualize urological cancers, particularly bladder, and improve their detection and resection."

The U.S. market is a leading global market for urology procedures. Bladder cancer is the fifth most common cancer. In 2013, the National Cancer Institute estimates there was 500,000 people living with bladder cancer in the United-States, 72,570 new cases and 15,210 deaths associated with the disease*. In 2011, sales of urology devices in the U.S. market were \$4.4 billion, accounting for 56.9% of the world's market.

Sacha Loiseau, CEO and founder of Mauna Kea Technologies, added, "This 510(k) clearance follows our recent AQ-Flex 510(k) clearance for needle-based microscopic imaging applications and further demonstrates our ability to expand our market opportunities for the Cellvizio platform in new indications. We are currently evaluating the best options to bring our advanced endomicroscopy technology to the market and thus to patients affected by serious urologic conditions as quickly as possible."

*Source : <http://www.cancer.gov/cancertopics/types/bladder>

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company dedicated to the advent of optical biopsy. The company researches, develops and markets innovative tools to visualize and detect cellular abnormalities during endoscopic procedures. Its flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers high-resolution cellular views of tissue inside the body. Large, international, multicenter clinical trials have demonstrated Cellvizio's ability to help physicians more accurately detect early forms of disease and make treatment decisions immediately. Designed to improve patient outcomes and reduce costs within a hospital, Cellvizio can be used with almost any endoscope. Cellvizio has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use during digestive and pulmonary endoscopy procedures, including pancreatic and biliary endoscopic explorations as well as fine needle aspiration procedures. Mauna Kea Technologies also obtained CE mark for a complete range of probes dedicated to urology.

For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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