



Mauna Kea Technologies obtains first ever FDA clearance for applications of Cellvizio® Confocal Laser Endomicroscopy in Neurosurgery

*Pivotal regulatory milestone in high stakes applications
Cellvizio first-to-market in key neurosurgery field
Provides unique response to unmet needs during brain and spinal surgeries*

Paris and Boston, May 24, 2018 – 5.45 PM CEST – Mauna Kea Technologies (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy (CLE) platform, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance of the Cellvizio® 100 series F400 and F800 with a new Confocal Miniprobe™, the CranioFlex™, to be used during neurosurgical procedures. This marks the 15th U.S. FDA 510(k) clearance of Cellvizio® and the first-ever FDA clearance for CLE applications in neurosurgery.

The Cellvizio® 100 with the CranioFlex™ provides imaging of tissue internal microstructures and allows the identification of cells and vessels and their organization within the central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection. The Cellvizio 100 series F400 model operates at 488 nm and the F800 model at 800 nm, two highly relevant wavelengths commonly used during brain surgery for imaging and navigation.

“This is an important regulatory and business milestone for the Company, opening new avenues for market development and strategic partnerships,” said Sacha Loiseau, Ph.D., Founder and Chief Executive Officer of Mauna Kea Technologies. “It also unlocks a new era in neurosurgery, paving the way toward more precise resection of brain and spinal tumors. Cellvizio® is now the first to market endomicroscopic visualization platform providing neurosurgeons for the first time the ability to perform real-time optical biopsies to help determine, for instance, if the tumor is completely excised. This clearance builds on many years of clinical development and is happening at a time when the neurosurgery community recognizes the potential benefits of real-time digital visualization of nervous system tissue microstructures.”

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time *in vivo* microscopic visualization. The Company’s flagship product, Cellvizio®, has received clearance/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

United States

Robert Flamm / Emma Poalillo
The Ruth Group
646-536-7017 / 7024
rflamm@theruthgroup.com / lroth@theruthgroup.com

U.S. Media

Kirsten Thomas
The Ruth Group
508-280-6592
kthomas@theruthgroup.com

France and Europe

NewCap - Investor Relations
Tristan Roquet Montégon
+33 (0)1 44 71 94 94
maunakea@newcap.eu

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