Mauna Kea Technologies Receives U.S. FDA 510(k) Clearance of its Next-Generation Cellvizio® Platform Combined with a Fluorescent Contrast Agent

The next-generation Cellvizio® platform is now cleared for use with fluorescein dye to image blood flow in the microvasculature and capillaries as a combination drug-device

Paris and Boston, August 24, 2021 – 05:45 PM CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its next-generation Cellvizio® platform and all associated Confocal Miniprobes™ for a new clinical indication for visualization of blood flow when used in conjunction with a fluorescent dye, fluorescein, as a drug-device combination (K212322). This marks the 19th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.

The next-generation Cellvizio® platform has already been cleared by U.S. FDA 510(k) for the vizualisation of the internal microstructure of tissues including, but not limited to, the identification of cells and vessels and their organization or architecture (K193416). Building upon the success of the previous models, the new generation of Cellvizio equips physicians with the most advanced cellular imaging technology to improve patients' lives. The platform includes several new features: an all-new workflow for endoscopic, bronchoscopic, or operating environments via integrated connectivity; enhanced capabilities enabling artificial intelligence (AI) for assisted pattern recognition; and a small footprint and slim profile allowing easy maneuverability within the procedure room. The Cellvizio® real-time *in vivo* cellular imaging platform is used in the fields of gastroenterology, pulmonology, and urology during endoscopic procedures, as well as laparoscopic and robot-assisted surgeries.

"This new FDA clearance of our next-generation Cellvizio platform in combination with a fluorescent dye is an additional validation of Cellvizio's unique capability to image, in real time, *in vivo* and at the cellular level, blood flow in the microvasculature and capillaries and represents a major regulatory milestone for Mauna Kea Technologies" commented Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. "Our next-generation Cellvizio platform will be presented, in-person, to the international community of gastroenterologists and GI surgeons during the American Foregut Society (AFS) and Viszeralmedizin (DGVS) conferences in September in Nashville, Tennessee, and Leipzig, Germany, respectively, and is now available to order as part of our formal commercial launch."

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real-time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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