Mauna Kea Technologies Announces Strong Advocacy from the American Foregut Society (AFS) for Broad Reimbursement Coverage from U.S. Commercial Payors for Cellvizio

New letter published by the AFS highlights Cellvizio's superiority to conventional tools for detecting pre-cancerous tissue and dysplasia

Paris and Boston, September 08, 2025 – 5:45 p.m. CEST – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that the American Foregut Society (AFS), a leading society of gastroenterologists and surgeons collaborating to improve patient outcomes of several conditions, including esophageal disease, has issued a new comprehensive letter¹ strongly advocating for broad reimbursement coverage of Cellvizio and confocal laser endomicroscopy (CLE) from commercial payors.

The letter highlights compelling clinical and economic data evidence, published recently, demonstrating Cellvizio's overwhelming sensitivity to the current "gold standard" of random biopsies (Seattle protocol four-quadrant biopsies) for patients with Barrett's esophagus, a precursor to esophageal cancer, and dysplasia detection.

Often considered as a non-followed gold standard, the Seattle protocol suffers from multiple issues leading to significant sampling error and missed diagnoses. The letter concludes that adjunctive use of Cellvizio leads to more accurate and timely diagnosis, enhances cost efficiency, and ultimately provides physicians with a greater range of options for patient management and treatment through earlier detection.

This advocacy reflects the society's recognition that despite overwhelming clinical evidence supporting Cellvizio, coverage limitations have prevented many patients from receiving the most accurate diagnostic evaluation available. As a result, the AFS strongly calls for broad reimbursement coverage of Cellvizio and CLE from commercial payors, so that all patients at risk for Barrett's esophagus and pre-cancerous changes have access to a comprehensive examination and endoscopic treatment prior to progression to esophageal cancer.

Sacha Loiseau, Chairman and CEO of Mauna Kea Technologies, added: "On behalf of the millions of patients suffering from reflux disease, we applied the AFS and look forward to working with payors to expand further the coverage of Cellvizio, ultimately broadening patient access to our breakthrough imaging platform. This endorsement builds on the commercial momentum we established in the U.S. during the first half, which has continued in the current quarter across both capital sales and our pay-per-use business".

¹ https://www.americanforegutsociety.org/assets/docs/research/AFS%20Position%20Paper-%20CLE%20.docx

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.

Mauna Kea Technologies

investors@maunakeatech.com

NewCap - Investor Relations

Aurélie Manavarere / Thomas Grojean +33 (0)1 44 71 94 94 maunakea@newcap.eu

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