Mauna Kea Technologies PRESS RELEASE

Mauna Kea Technologies Receives NMPA Regulatory Approval in China for its Next-Generation Cellvizio® Platform

NMPA approval obtained following a 3-year certification process

Mauna Kea is now evaluating options to commercialize Cellvizio Gen 3 in China independently of the JV with Tasly

Paris and Boston, November 20, 2025 – 5:45 p.m. CET – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that it has obtained approval from the National Medical Products Administration (NMPA) in China for the import and commercialization of its next-generation Cellvizio (Gen 3) platform.

This registration was processed and obtained directly by Mauna Kea Technologies S.A. and is valid for five years until November 2030. It authorizes the use in China of the Gen 3 platform in conjunction with the Company's full range of confocal probes (GastroFlex™ N, ColoFlex™ N, CholangioFlex™ N, AlveoFlex™ N, AQ-Flex™ 19 N).

The Cellvizio® Gen 3 system is the Company's most advanced platform and is a distinct asset not included in the previous agreements under the Joint Venture with Tasly. By securing this approval directly, Mauna Kea reinforces its portfolio of proprietary assets in China.

China represents an important market for interventional endoscopy, with strong demand for precision diagnostic technologies. With this essential regulatory authorization now in place, Mauna Kea is currently evaluating its options for the commercialization of the next-generation Cellvizio® platform to Chinese hospitals, aiming to make this cutting-edge technology available to practitioners and patients as effectively as possible.

Sacha Loiseau, Chairman, CEO, and founder of Mauna Kea Technologies, commented**:** *"The approval of our Cellvizio Gen 3 in China is excellent news as it reopens the Chinese market, a very important territory for endoscopy where we historically have had significant activity. This approval positions us as the most advanced technology relative to the competition that exists specifically in this market. We will move quickly to evaluate and identify the best options that will allow us to commercialize our new platform as soon as possible, which would represent upside revenue compared to our current business plan."*

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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Disclaimer

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