



Mauna Kea Technologies Announces Success of Clinical Trial on Prediction of Remission in Patients with Inflammatory Bowel Disease (IBD) and its Publication in *Gastroenterology*

Dynamic monitoring of the intestinal barrier with Confocal Laser Endomicroscopy demonstrated to be far superior to endoscopic and histologic biomarkers as predictors of long-term remission

Intestinal Barrier Healing emerges as a new key therapeutic endpoint for IBD

Paris and Boston, October 31, 2022 - 5:45 p.m. CET - Mauna Kea Technologies (Euronext: MKEA), inventor of Cellvizio®, the multi-disciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announced the success of a long term prospective clinical study on the prediction of major adverse outcomes for patients suffering from Inflammatory Bowel Disease (IBD) using Confocal Laser Endomicroscopy with Cellvizio®. Final results of the ERICA trial (Erlangen Remission in IBD, clinicaltrials.gov NCT05157750) are now published in the peer-reviewed journal *Gastroenterology*, the flagship journal of the American Gastroenterological Association, in the article *“Intestinal barrier healing is superior to endoscopic and histologic remission for predicting major adverse outcomes in IBD: the prospective ERICA trial”*¹.

Endoscopy is the key technique for the surveillance of patients suffering from IBD, with patients undergoing surveillance colonoscopy every one to two years. Endoscopic and histologic remission, characterized by visual assessment of the colon and analysis of random biopsies, have emerged as key therapeutic goals in the management of IBD that are associated with favorable long-term disease outcomes.

In this study, the authors prospectively compared the predictive value of intestinal barrier healing visualized dynamically and functionally in real time with Confocal Laser Endomicroscopy (Cellvizio®) versus endoscopic and histologic remission for predicting long-term disease behavior in a large cohort of IBD patients in clinical remission.

Prof. Dr. med. Timo Rath, Head of the Ludwig Demling Endoscopy Center of Excellence at the University Hospital Erlangen, said: *“Our data clearly show that intestinal barrier healing, as assessed by dynamic and functional visualization with Confocal Laser Endomicroscopy is a prognostic parameter that by far outcompetes endoscopic and histologic remission, or their combination, in the forecasting of the occurrence of major clinical events in both Ulcerative Colitis and Crohn’s Disease patients. This has far-reaching consequences on the way patients suffering from these debilitating diseases should be monitored during remission.”*

“The importance of these new clinical results for the 6 to 8 million people who suffer from Inflammatory Bowel Disease globally could not be overstated as they are paving the way to a much improved management of their condition, and in particular how the colonoscopies they are undergoing every one to two years are being conducted”, said Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies. *“This remarkable clinical study, led by some of the world’s authorities on IBD, further exemplifies Cellvizio’s differentiated value proposition as the unique advanced imaging solution providing real-time, dynamic and functional cellular imaging of tissues. This publication in the leading peer-reviewed journal in the field of gastroenterology confirms the essential role that Cellvizio can play in the way physicians monitor and treat their patients with IBD and how new therapeutic targets can be designed.”*

¹ [https://www.gastrojournal.org/article/S0016-5085\(22\)01192-1/fulltext](https://www.gastrojournal.org/article/S0016-5085(22)01192-1/fulltext)

**Key clinical results:**

Between 2017 and 2019, a total of 296 IBD patients were screened for eligibility. Out of these, 181 IBD patients (100 with Crohn's Disease (CD) and 81 with Ulcerative Colitis (UC)) patients were finally eligible and included in the study, with a mean follow-up of 25 months for UC and 35 months for CD.

Endoscopic and histologic disease activity as well as barrier healing were prospectively assessed along established scores. During subsequent follow-up, patients were closely monitored for clinical disease activity and the occurrence of major adverse outcomes (MAO): disease flares, IBD-related hospitalization or surgery, initiation or dose escalation of systemic steroids, immunosuppressants, small molecules or biological therapy.

The authors found that Barrier Healing assessed with Confocal Laser Endomicroscopy was far superior to endoscopic and histologic remission for predicting MAO-free survival in both UC and CD:

- For patients suffering from UC and with Barrier Healing in the Colon confirmed with Cellvizio, the MAO-free survival probability was 81% compared to 47.7% - 64.7% for all other predictors.
- For patients suffering from CD and with Barrier Healing in the Colon confirmed with Cellvizio, the MAO-free survival probability was 70.4% compared to 43.9% - 50% for all other endoscopic and histologic predictors. When Barrier Healing was confirmed in the Ileum, this probability reached 100% compared to 43.9% - 50% for all other predictors.

About Inflammatory Bowel Disease (IBD)

Inflammatory Bowel Disease (IBD) is a term for two conditions (Crohn's disease and ulcerative colitis) that are characterized by chronic inflammation of the gastrointestinal (GI) tract. Prolonged inflammation results in damage to the GI tract and possibly cancer. More than 6-8 million people globally including 2 million Europeans and 3 million North Americans have IBD, with the majority of health-care costs driven by medication. The cause of IBD is unknown, but it is considered to be the result of an inappropriate immune response against environmental factors, including luminal and microbial antigens, in genetically susceptible hosts.

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and markets Cellvizio®, the real-time in vivo cell imaging platform. This technology provides unique in vivo cellular visualization that allows physicians to monitor disease progression over time, assess responses as they occur, classify areas of uncertainty and guide surgical interventions. The Cellvizio platform is used in many countries around the world and in several medical specialties and is transforming the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

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