



Mauna Kea Technologies Announces a New Publication in Nature Scientific Reports Demonstrating the Accuracy of Cellvizio® for Food Allergy Diagnosis

New peer-reviewed evidence that Cellvizio can be used as a screening tool in patients with suspected food allergy

Paris and Boston, June 22, 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 a peer-reviewed publication in the journal Nature Scientific Reports entitled “Cross-sectional imaging of intestinal barrier dysfunction by confocal laser endomicroscopy can identify patients with food allergy *in vivo* with high sensitivity” (2021, <https://www.nature.com/articles/s41598-021-92262-4>). This paper provides new evidence that Cellvizio®, thanks to its unique capability to perform real-time functional imaging *in vivo* and at the cellular level, can accurately diagnose patients with food allergies.

Food allergy diagnosis is challenging and relies on commonly used allergy tests such as skin prick testing or serum-radioallergosorbent tests which exhibit limited sensitivity and specificity. Therefore, oral food challenge with increasing doses of a potential antigen over a defined period of time remains the diagnostic gold standard for food allergy. However, since oral food challenge is resource-intensive and requires vigilant cooperation between patient, physician, and nutritionist, it is infrequently used outside specialized centers.

This study provides new clinical evidence that Cellvizio (pCLE) imaging of the intestinal barrier during routine colonoscopy can accurately detect, *in vivo* and in real time, patients with food allergy.

“pCLE-based imaging is highly sensitive at 96% for the *in vivo* diagnosis of food allergy. Further, with a high negative predictive value of 96%, these new results indicate that pCLE can be used as a screening test that will allow stratifying patients with suspected food allergy for further diagnostic work-up,” said Prof. Dr. med. Timo Rath, Professor of Endoscopy and Molecular Imaging, Head of the Ludwig Demling Endoscopy Center of Excellence, and Endoscopic Research at University Hospital Erlangen in Erlangen, Germany, the first author of this publication.

“This is a very exciting study exploring the clinical potential of Cellvizio’s advanced, *in vivo*, imaging technology to screen patients with suspected food allergy,” said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. “Patients with life-altering symptoms can go years without a clear assessment of their conditions due to the limited predictive value of common tests. This new high-quality study confirms that Cellvizio imaging has a very high sensitivity and negative predictive value for food allergy and can thus considerably improve patient care. With 3-4% of the adult population in western countries affected by food allergy¹, the size of the market that we can address with this application is very large. As we recently announced, we have 15 centers in Europe performing this functional test with Cellvizio. We look forward to many more centers coming on line with a high number of patients in the coming quarters.”

¹ Hill DA, Grundmeier RW, Ram G, Spergel JM. The epidemiologic characteristics of healthcare provider-diagnosed eczema, asthma, allergic rhinitis, and food allergy in children: a retrospective cohort study. BMC Pediatr. 2016 Aug 20;16:133. doi: 10.1186/s12887-016-0673-z. PMID: 27542726; PMCID: PMC4992234.



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 revolutionizing the way physicians diagnose and treat patients — making a transformative change in medicine. For more information, visit www.maunakeatech.com.

United States

Mike Piccinino, CFA
Westwicke, an ICR Company
443-213-0500

France and Europe

NewCap - Investor Relations
Thomas Grojean
+33 (0)1 44 71 94 94
maunakea@newcap.eu

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