

Mauna Kea Technologies Unveils CellTolerance, a Subsidiary Dedicated to its Unique Program for the Detection and Treatment of Food Intolerances

CellTolerance™ is a unique science-based program designed with physicians and dietitians

New data presented at Digestive Disease Week 2024 reinforces the program's unique clinical value for patients

Initiation of discussions with clinic networks to establish strategic partnerships for rapid expansion into a market estimated at \$1.5bn

Development of digital tools and unique multi-scale datasets to create AI solutions for pharmaceutical and nutrition companies

Paris and Boston, June 26, 2024 – 5:45 pm CEST – Mauna Kea Technologies (Euronext Growth: **ALMKT), inventor of Cellvizio®, the multidisciplinary platform for probe-based and needle-based confocal laser endomicroscopy (p/nCLE), unveils its new subsidiary CellTolerance¹, fully dedicated to its unique program for the detection and treatment of food intolerances associated with Irritable Bowel Syndrome (IBS).**

“CellTolerance™ represents a significant advancement in the detection and treatment of food intolerances. By integrating cutting-edge science with practical clinical applications, we are about to revolutionize how millions of patients manage their food-related Irritable Bowel Syndrome and their overall health. Our commitment to leveraging AI and data analytics could not only enhance patient outcomes but also provide invaluable insights to the broader nutrition and pharmaceutical industries. We are excited to embark on this journey and look forward to forming strategic partnerships that will help us rapidly expand our reach and impact”, said **Sacha Loiseau, Chairman and CEO of Mauna Kea Technologies.**

¹ Wholly owned by Mauna Kea Technologies, the company CellTolerance is in the process of being incorporated. More information on: www.cell-tolerance.com

A significant unmet medical need affecting 1 in 10 people

More than 50 million patients² suffer from food intolerances associated with IBS in the U.S. and Europe – nearly 1 person in 10 – and more than half of them could suffer from atypical food allergies, which can be difficult to identify and treat. In a recent large-scale survey³, 64% of IBS patients reported suffering for more than 10 years, and 33% described their symptoms as completely out of control. Current treatments frequently fail to provide relief, leaving a substantial portion of this population with ongoing discomfort and health issues.

Strong clinical science and real-world evidence of CellTolerance™ proven to reduce symptoms in 96% of patients⁴

CellTolerance™ is a unique program designed with physicians and dietitians to detect and treat food intolerances through personalized dietary monitoring, live cell-response visualization via intestinal barrier microscopic response to selected foods and supervised elimination diets. It is rooted in more than a decade of research and peer-reviewed publications, including new data presented at the Digestive Disease Week® (DDW) 2024 Conference held in Washington, DC.

As part of a baseline medical workup for IBS, patients are asked to respond to a standardized IBS-symptom severity score (IBS-SSS). In one abstract presented at DDW⁵ researchers found that patients who underwent a CellTolerance-guided food elimination diet saw a significant reduction in their IBS-SSS compared to the pre-test baseline ($p = 0.04$). More interestingly, patients saw a significant worsening of symptoms when that particular food was reintroduced ($p = 0.04$), underscoring the positive impact of identifying the correct food with an accurate test like CellTolerance™. In a separate oral presentation at DDW⁶, CellTolerance™ was presented as a viable screening tool to detect food intolerances in patients who have previously tested negative for IgE-mediated food allergies or celiac disease but continue to have suspected food-related IBS symptoms. Thanks to dedicated and visionary physicians, hundreds of patients have already experienced a CellTolerance-guided elimination diet and 96% have reported improvement of their symptoms, higher than the difficult-to-implement low-FODMAP diet⁷.

² <https://doi.org/10.1046/j.1365-2036.2003.01456.x>

³ YouGOVSURVEY to patients with IBS, March 2024

⁴ <https://doi.org/10.1053/j.gastro.2019.03.046>

⁵ [https://doi.org/10.1016/S0016-5085\(24\)03619-9](https://doi.org/10.1016/S0016-5085(24)03619-9)

⁶ <https://doi.org/10.1016/j.gie.2024.04.2600>

⁷ [http://dx.doi.org/10.1016/S0016-5085\(20\)31016-7](http://dx.doi.org/10.1016/S0016-5085(20)31016-7)

A new company dedicated to digital health and AI solutions

To best develop the CellTolerance™ program, a new wholly owned subsidiary will soon be incorporated (“CellTolerance”), with the prospect of eventually operating as an independent, lean company with specific agreements, ensuring the availability of the Cellvizio technology platform as a key component of the CellTolerance™ program.

CellTolerance will also aim at providing patients, providers and partners with innovative digital tools to monitor patients and collect a vast quantity of real world and clinical data. This unique multi-scale dataset (endoscopy, endomicroscopy, clinical data, etc.) will be leveraged to develop advanced AI models offering unprecedented clinical insights. These insights could empower pharmaceutical and nutrition companies to tailor personalized treatments, optimize nutritional plans, and predict individual responses to therapies and dietary interventions.

By integrating comprehensive data analytics and AI, CellTolerance aims to transform healthcare delivery and nutrition management, ultimately enhancing patient outcomes and advancing medical research.

It is also envisioned that CellTolerance will quickly open its capital to venture capital funds specializing in nutrition, wellness, microbiome, gut health and related activities to fund the development of its program independently.

A market opportunity estimated at \$1.5 billion⁸ to be addressed through strategic partnerships

The CellTolerance™ program is intended to be launched at scale in key markets such as the United States, France, Germany, Italy and Switzerland. The addressable market in these countries is highly significant, representing an opportunity estimated at \$1.5 billion. To best capitalize on this opportunity and maximize the reach of its program, CellTolerance intends to form strategic partnerships with clinic networks which see the program as a unique opportunity to expand their service offerings.

By working closely with networks of clinics, CellTolerance will ensure continuous training and ongoing support for healthcare professionals, enabling optimal use of its technologies. This strategy aims to establish CellTolerance™ as the reference solution for identifying and treating food intolerances while reducing marketing costs through partners' marketing infrastructures.

⁸ Source: Company

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 18-21, 2024. The meeting showcases more than 5,600 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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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