GASTRO OFFICE BREAKS NEW GROUND FOR PATIENTS BY BECOMING THE FIRST PRACTICE IN OHIO TO USE CELLVIZIO TO IMPROVE THE DIAGNOSIS AND TREATMENT OF BARRETT'S ESOPHAGUS

Cellvizio, from Mauna Kea Technologies, is the only device that uses confocal laser endomicroscopy (CLE) to give physicians the power to see in vivo real-time cellular changes and responses to therapies

Boston (May 31, 2023) – Patients in Ohio who suffer from persistent heartburn, reflux, and upper gastrointestinal pain and discomfort now have access to advanced imaging technology that can deliver a more accurate diagnosis in less time, thanks to Gastro Office. Hilliard Endo Center in Hilliard, OH is a surgery center affiliated with Gastro Office, which became the first center in Ohio to use Cellvizio® for these health conditions.

Cellvizio, which was created by Mauna Kea Technologies (Euronext: MKEA), is the only multidisciplinary probe and needle-based confocal laser endomicroscopy (CLE) platform that allows physicians to see cellular changes within the gastrointestinal tract and other areas of the body in real time. This in vivo cellular imaging gives physicians the ability to more accurately diagnose diseases like Barrett's Esophagus (BE), for which heartburn and reflux are common symptoms, and to monitor the efficacy of treatment.

Gastro Office implemented Cellvizio in February and has already conducted nearly 100 endoscopic procedures with this advanced technology.

"Heartburn is one of the most common digestive complaints for patients, but the root cause can be difficult to detect and pinpoint and, if left untreated, can lead to cellular changes within the gastrointestinal tract. At Gastro Office, we focus solely on digestive health, including conditions like reflux, BE, and cancers," said Krishna Rayapudi, M.D., DABOM., CEO of Gastro Office and Hilliard Endo Center. "Patients who come in for endoscopy procedures appreciate that they are getting the most advanced technology available in Cellvizio, and as physicians, we appreciate the flexibility and improved visibility Cellvizio provides. More importantly, we anticipate that this will begin to inform pathology results over time."

Accurate diagnosis and monitoring of BE is critical, especially considering that 5% of BE cases evolve into Esophageal Cancer (EAC) within five years of the initial BE diagnosis. Meanwhile, the incidence of esophageal cancer continues to grow rapidly. The ability to monitor real-time cellular changes within the esophagus enables physicians to remove precancerous tissue in the hopes of preventing further spread of the disease.

Gastro Office serves patients in the greater Columbus, OH area, treating conditions that affect the health of the digestive tract, including the esophagus, stomach, small and large intestines, pancreas, gallbladder, bile ducts, and liver.

To learn more about their services, visit
GastroOffice.com
or call 614-385-5900

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.

TAKEDA ANNOUNCES FDA ACCEPTANCE OF BLA RESUBMISSION FOR INVESTIGATIONAL SUBCUTANEOUS ADMINISTRATION OF ENTYVIO® (VEDOLIZUMAB) FOR MAINTENANCE THERAPY IN MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

OSAKA, Japan and CAMBRIDGE, Massachusetts, April 27, 2023 – Takeda (TSE:4502/NYSE:TAK) ("Takeda") announced that the U.S. Food and Drug Administration (FDA) has accepted for review its Biologics License Application (BLA) resubmission for the investigational subcutaneous (SC) administration of Entyvio® (vedolizumab) for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) after induction therapy with Entyvio intravenous. The resubmission is intended to address FDA feedback in a December 2019 Complete Response Letter (CRL).

"Takeda has remained committed to the pursuit of a subcutaneous administration for Entyvio in the U.S. so that patients might have a choice between receiving Entyvio maintenance therapy via intravenous infusion by a health care professional or administering it themselves with a single-dose injection – whichever suits their medical and personal needs. This resubmission is a major step forward in delivering on that commitment," said

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Vijay Yajnik, M.D., Ph.D., vice president,head of U.S. Medical for Gastroenterology, Takeda. "We have great confidence in the future of Entyvio SC and strongly believe that offering a SC formulation can help meet the varied needs of patients who live with moderate to severe ulcerative colitis, pending approval."

Since receiving the CRL Takeda has worked closely with the FDA to address the Agency's feedback; this resubmission package includes additional data collected to investigate the use of subcutaneous administration of Entyvio. The contents of the letter were unrelated to the intravenous (IV) formulation of Entyvio, the clinical safety and efficacy data, and conclusions from the pivotal VISIBLE 1 trial supporting the Entyvio SC BLA.

VISIBLE 1 assessed the safety and efficacy of a SC formulation of Entyvio as maintenance therapy in 216 adult patients with moderately to severely active UC who achieved clinical response* at week 6 following two doses of open-label vedolizumab intravenous therapy at weeks 0 and 2.[1] The primary endpoint was clinical remission at week 52, which was defined as a total Mayo score of ≤2 and no subscore >1.[1]

Takeda expects a decision from the FDA by the end of 2023.

* Clinical response is defined as a reduction in complete Mayo score of ≥3 points and ≥30% from baseline (week 0) with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point.[1]

About Entyvio® (vedolizumab)

Vedolizumab is a biologic therapy and is approved in intravenous (IV) and subcutaneous (SC) formulations (approvals vary by market; vedolizumab is not currently approved in the SC formulation in the U.S.).[2,3] Vedolizumab SC has been granted marketing authorization in the European Union and more than 50 countries. Vedolizumab IV has been granted marketing authorization in more than 70 countries, including the United States and European Union, with more than 1,000,000 patient years of exposure to date.[4] It is a humanized monoclonal antibody designed to specifically antagonize the alpha4beta7 integrin, inhibiting the binding of alpha4beta7 integrin to intestinal mucosal addressin cell adhesion molecule 1 (MAdCAM-1), but not vascular cell adhesion molecule 1 (VCAM-1).[5] MAdCAM-1 is preferentially expressed on blood vessels and lymph nodes of the gastrointestinal tract.[6] The alpha4beta7 integrin is expressed on a subset of circulating white blood cells.[5] These cells have been shown to play a role in mediating the inflammatory process in ulcerative colitis (UC) and Crohn's disease (CD).[5,7,8] By inhibiting alpha4beta7 integrin, vedolizumab may limit the ability of certain white blood cells to infiltrate gut tissues.[5]

Adult Crohn's Disease (CD)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD.

About Ulcerative Colitis and Crohn's Disease

Ulcerative colitis (UC) and Crohn's disease (CD) are two of the most common forms of inflammatory bowel disease (IBD).[9] Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the gastrointestinal tract.[10,11] UC only involves the large intestine as opposed to CD which can affect any part of the GI tract from mouth to anus.[12,13] CD can also affect the entire thickness of the bowel wall, while UC only involves the innermost lining of the large intestine.[12,13] UC can present with symptoms of abdominal discomfort or loose bowel movements, including blood.[12,14] CD can present with symptoms of abdominal pain, diarrhea, and weight loss.[10] The cause of UC or CD is not fully understood; however, research suggests that an interplay between environmental factors, genetics, and intestinal microbiota may contribute to the development of UC or CD.[12,15,16]

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