

UPDATED STANDARD OF CARE GUIDELINES POINT TO CAIRN BREATH TEST TO EVALUATE GASTRIC EMPTYING & DIAGNOSING GASTROPARESIS

BRENTWOOD, TENNESSEE, September 14, 2023/EINPresswire.com/ – Cairn Diagnostics, an innovative leader in providing cutting-edge FDA-approved breath tests intended for routine use in diagnostic medicine, today announced the inclusion of its 13C-Spirulina Gastric Emptying Breath Test (GEBT), in recently updated American, European and International Consensus Clinical Guidelines* for evaluation of gastric emptying and diagnosis of gastroparesis (“paralysis of the stomach”) in patients ages 18 years and older.

Gastroparesis is a debilitating disease in which the stomach empties at an abnormally slow pace and is defined by delayed gastric emptying in the absence of mechanical obstruction. It is characterized by recurrent symptoms such as nausea, vomiting, early satiety, postprandial fullness, abdominal discomfort, and pain. Gastroparesis has clinical origins arising from diabetes, hypothyroidism, nervous system disorders, autoimmune disorders, viral infections, surgery and idiopathic (unknown) reasons.

Awareness of gastroparesis in the clinical and obesity management community is increasing, with a growing number of gastroparesis cases now resulting from drug interventions such as narcotic pain medications and popular drugs used to treat diabetes and obesity. Semaglutide, in particular, is a drug that slows gastric emptying, making patients feel full and decreasing their appetite, which helps facilitate weight loss and improves glycemic control. Semaglutide is the active ingredient in familiar drugs such as Ozempic, Wegovy and Rybelsus. If these drugs are prescribed to patients that are unknowingly predisposed to gastroparesis, or if the dosage is not carefully titrated to recommended dosage protocols, this can induce moderate to severe gastroparesis.

Historically, clinical guidelines for diagnosis of gastroparesis have recommended using a radioactive 4-hour gastric emptying study conducted in a nuclear medicine center: a procedure known as Gastric Emptying Scintigraphy (GES). Today, clinicians and patients may alternatively choose Cairn’s innovative GEBT, a safe, non-radioactive, non-invasive, orally administered,

FDA-approved, and standardized test to measure rates of gastric emptying and to help diagnose gastroparesis. GEBT does not require nuclear medicine imaging equipment, specially licensed facilities or personnel, or radioactive material. The test can be administered in a clinical practice or by virtually supervised telehealth conveniently in a patient’s home. Upon receipt of a patient’s breath samples at Cairn’s CLIA Laboratory, results can be reported within 24-48 hours. GEBT is now covered by Medicare (CMS) and is commercially available in the U.S.

“Gastroparesis affects over 5 million people in the U.S.i We have an obesity crisis (approximately 40 percent of Americans being overweight), along with high prevalence of gastroparesis in diabetics, serious gastroparesis-related adverse events associated with popular weight loss drugs, and reluctance to give deep sedation to patients scheduled for endoscopy or surgery who are taking semaglutide,” said Kerry Bush, President & COO, Cairn Diagnostics. “Given the significantly elevated gastroparesis conversation among physicians, these recently updated U.S., EU and international standard of care guidelines underscore the need for the GEBT – a more widely available method for helping to rapidly diagnose this disease and improve health outcomes.”

GEBT provides a more convenient, timely modality for assessing gastric emptying, particularly in susceptible populations such as diabetics, idiopathic gastroparetic patients, neurologically affected patients, and tender populations where radiation is best avoided. Examples include: patients and clinicians preferring to avoid radiation (gastroparesis is 4 times more prevalent in women than men); patients needing more than one evaluation; those living in smaller and rural communities where nuclear medicine assets are unavailable; and those encountering long scheduling times (up to 3 months) for the nuclear medicine procedure in major metropolitan areas (including academic medical centers), causing delays in evaluation and diagnosis. Contrary to nuclear medicine-based GES, GEBT is always conducted in exactly the same manner over a 4-hour period per Clinical Guideline recommendations.

GEBT was validated in FDA-approved,

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dual-labeled clinical validation studies (Mayo Clinic, Rochester) against the 4-hour radioactive Gastric Emptying Scintigraphy (GES) procedure, which is considered the conventional method of assessing gastric emptying and must be conducted in specially licensed nuclear medicine facilities.ⁱⁱ

About Cairn Diagnostics

Cairn Diagnostics provides safe, validated, standardized, FDA-approved, and conveniently administered diagnostic breath tests. The Company serves community-based practices and partners with university-based academic researchers, medical device, and pharmaceutical companies. Cairn received FDA approval for GEBT in 2015, expanded FDA approval of GEBT to include “at home” administration under virtual supervision in 2021, and inclusion in ACG and AGA Guidelines for evaluating Gastroparesis in 2022. Cairn also recently (2023) received FDA approval for a new generation of high precision gas isotope ratio mass spectrometers (GIRMS) for analyzing GEBT breath specimens making analysis, test reporting and time to diagnosis even faster.

Cairn was also granted an exclusive CPT PLA Code (0106U) by AMA in July 2019, and received CMS (Medicare) coverage approval in July 2020. Medicare’s coverage decision for GEBT was based on the test’s “analytic and clinical validity as well as clinical utility in the diagnosis of gastroparesis.”ⁱⁱⁱ The GEBT CPT code, Code Description, and Medicare payment rate was published in the National Clinical Laboratory Fee Schedule in January 2021. Cairn currently holds the intellectual property on 14 patents and one pending patent.

For more information, visit:

cairndiagnostics.com

- i. Centers for Disease Control and Prevention. Long-term Trends in Diabetes. CDC’s Div Diabetes Transl.
 - ii. Szarka L, et al. A stable isotope breath test with a standard meal for abnormal gastric emptying of solids in the clinic and in research. *Clinical Gastroenterology and Hepatology*. June 2008; 6(6):635-643. Available at <http://www.ncbi.nlm.nih.gov/pubmed/18406670>
 - iii. Jurisdictions JJ, JM and MoIDx, Palmetto GBA, July 2020; Billing & Reimbursement – 13C-Spirulina GEBT. Accessed June 24, 2021. <https://cairndiagnostics.com/billing/>
- * ACG Clinical Guideline: Gastroparesis: https://journals.lww.com/ajg/Fulltext/2022/08000/ACG_Clinical_Guideline_Gastroparesis.15.aspx?context=FeaturedArticles&collectionId=2

LILLY'S MIRIKIZUMAB HELPED PATIENTS WITH CROHN'S DISEASE ACHIEVE LONG-TERM REMISSION IN PHASE 3 TRIAL

- *Mirikizumab demonstrated clinical remission and endoscopic response for patients with moderately to severely active Crohn's disease through 52 weeks*
- *The study achieved the coprimary endpoints and all major secondary endpoints versus placebo*
- *This successful Phase 3 trial will be the basis of global regulatory submissions for Crohn's disease*

INDIANAPOLIS, Oct. 12, 2023/PRNewswire/—Eli Lilly and Company (NYSE: LLY) announced today that mirikizumab (an investigational interleukin-23p19 antagonist) met the co-primary and all major secondary endpoints compared to placebo in VIVID-1, a Phase 3 study evaluating the safety and efficacy of mirikizumab for the treatment of adults with moderately to severely active Crohn's disease. The double-blind, treat-through trial included mirikizumab, placebo and active control (ustekinumab) arms.

Crohn's disease is a form of inflammatory bowel disease (IBD) that can cause systemic inflammation manifested as abdominal pain, diarrhea, fever and weight loss. It can lead to intestinal obstruction, fibrosis and other complications.

In VIVID-1, all patients in the active treatment arms from the 12-week induction period continued with their original therapy into the maintenance portion of the study up to Week 52. Placebo patients who did not achieve clinical response at Week 12 (nonresponders) were switched to blinded mirikizumab treatment.

The study included co-primary endpoints, which were:

- Proportion of participants achieving clinical response by patient reported outcomes (PRO)* at Week 12 and clinical remission (defined as a Crohn's Disease Activity Index [CDAI] Total Score <150) at Week 52 compared to placebo
- In the mirikizumab arm, a statistically higher proportion achieved clinical response at Week 12 and clinical remission at Week 52 compared to placebo (45.4% versus 19.6%, p<0.000001)
- Proportion of participants achieving clinical response by PRO at Week 12 and endoscopic response (defined as ≥50% reduction from

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baseline in Simple Endoscopic Score – Crohn's Disease [SES-CD] Total Score) at Week 52 compared to placebo

- In the mirikizumab arm, a statistically higher proportion achieved clinical response at Week 12 and endoscopic response at Week 52 compared to placebo (38.0% versus 9.0%, $p < 0.000001$)

In this double-blind placebo and active controlled trial – the first reported for an IL-23p19 antibody – mirikizumab achieved all individual and composite major secondary endpoints at Week 52 compared to placebo ($p < 0.000001$). Notably, of the patients who received mirikizumab, 54.1% achieved clinical remission at Week 52 compared to 19.6% of patients who received placebo ($p < 0.000001$). In addition, for the endpoint of clinical remission (defined as CDAI < 150), mirikizumab demonstrated non-inferiority versus ustekinumab (non-inferiority margin of 10%). For the endpoint of endoscopic response ($\geq 50\%$ reduction from baseline in SES-CD Total Score) at Week 52, mirikizumab did not achieve superiority to ustekinumab although results with mirikizumab were numerically higher, particularly in the non-multiplicity controlled bio-failed population.

"I'm excited by these results, which showed more than half of patients on mirikizumab achieved clinical remission as measured by CDAI at one year. Furthermore, mirikizumab demonstrated robust efficacy across subgroups and particularly in patients for whom prior biologic therapy had failed," said Lotus Mallbris, M.D., Ph.D., senior vice president of immunology development at Lilly. "Many people are seeking relief from their uncontrolled Crohn's disease, including those still experiencing symptoms with available therapies such as TNF inhibitors. Helping patients achieve long-term clinical remission is what inspires us to develop innovative treatments for inflammatory bowel diseases, including Crohn's disease and ulcerative colitis."

The overall safety was consistent with the known safety profile of mirikizumab. The frequency of serious adverse events was greater in placebo than mirikizumab. The most common treatment-emergent adverse events reported among patients treated with mirikizumab were COVID-19, anemia, arthralgia, headache and upper respiratory tract infection. Additional adverse

events of interest reported among patients treated with mirikizumab included infections, injection-site reactions, hypersensitivity, liver enzyme elevations, depression and suicidal thoughts. No major adverse cardiac events were observed in the mirikizumab arm.

With these data, Lilly plans to submit a marketing application for mirikizumab in Crohn's disease to the Food and Drug Administration (FDA), followed by submissions to other regulatory agencies around the world, in 2024. Full data from the Phase 3 VIVID program will be disclosed in publications and at upcoming congresses.

* Clinical response by PRO is defined as $\geq 30\%$ decrease in stool frequency and/or abdominal pain, and neither score worse than baseline.

About Mirikizumab

Mirikizumab is an interleukin-23p19 antagonist that is currently indicated for the treatment of moderately to severely active ulcerative colitis (UC) in Japan, Germany, the United Kingdom and Canada. Mirikizumab selectively targets the p19 subunit of IL-23 and inhibits the IL-23 pathway. Inflammation due to over-activation of the IL-23 pathway plays a critical role in the pathogenesis of UC and Crohn's disease.

About Lilly

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news or follow us on Facebook, Instagram, Twitter and LinkedIn. P-LLY