AMBU ANNOUNCES 510(K) CLEARANCE OF SINGLE-USE GASTROSCOPE AND NEXT-GENERATION DISPLAY UNIT

Ambu Enters a Market Of 20 Million Annual Procedures, Expanding Presence in GI.

Ambu announced the 510(k) regulatory clearance of the Ambu® aScope™ Gastro and Ambu® aBox™ 2 in the United States. aScope Gastro is Ambu's first sterile single-use gastroscope and includes new advanced imaging and design features in a combined solution with next-generation display and processor technology. With HD capabilities, the aBox 2 will set a new benchmark in terms of image quality and will expand our advanced display offering.

Advanced technology to support doctors, health systems, and patients

With the launch of aScope Gastro, Ambu enters the upper GI segment, where 20 million procedures are performed annually with reusable endoscope systems.

The advanced technology, portability, and cost-effectiveness of Ambu's solution address the current limitations of reusable endoscopes, and it will be an attractive choice for customers looking to perform EGD or upper GI procedures across a wide range of care settings (including the endoscopy unit, OR, ICU, ER, and ambulatory surgery centers). Furthermore, the aScope Gastro will support healthcare systems in their efforts to reduce waiting lists and overcome staff shortages, which have been accentuated since the start of the COVID-19 pandemic. Finally, the sterile offering provides a solution to growing cross-contamination risks, especially for vulnerable patients.

"The Ambu system comes at a time where we're dealing with waiting lists and staff shortages, and where the ease of setup and elimination of reprocessing, are major advantages. Also, the combination of a sterile single-use gastroscope and a compact display unit opens up the opportunity to expand endoscopy to alternative settings, such as Intensive Care Units," says Prof. Pradeep Bhandari,[1] Queen Alexandra Hospital, Portsmouth, UK.

"In the OR setting, having a single-use scope that is immediately available with a small footprint, which requires much less up-front capital outlay than a reusable setup, will be valuable to many hospitals across the country," says Reginald Bell, M.D.,[1] F.A.C.S, Institute of Esophageal and Reflux Surgery, Lone Tree, Colorado, USA.

Ambu® aScope™ Gastro and Ambu® aBox™ 2 form a combined solution featuring a single-use gastroscope with a reusable display and processor unit.

A gastroscope enables a doctor to examine the esophagus, stomach, and duodenum of the patient. A procedure can take 10 minutes to more than an hour depending on the complexity of the case.

With this FDA clearance, Ambu will proceed with commercialization of the aScope Gastro and aBox 2 in the United States.

Expanding Ambu's presence in GI

Together with the launch of the aScope™ Duodeno, the aScope Gastro represents the next step in Ambu's expansion into the GI segment. They will be followed by a next-generation single-use duodenoscope (aScope Duodeno 2.0) as well as a colonoscope and a cholangioscope, giving Ambu the most comprehensive single-use portfolio in GI.

"Gastroscopy is not only one of the largest segments in endoscopy, it also has all the conditions

to benefit from single-use endoscopy. There is a clear need for more convenience, flexibility, and infection control, which are all addressed with the introduction of our aScope Gastro," says Juan Jose Gonzalez, CEO of Ambu. "The technology in our aScope Gastro and aBox 2 will set a new benchmark in terms of image quality and functionality and will power all of our next-generation launches. Our expansion within GI will extend Ambu's position as the world's most innovative single-use endoscopy player."

1. Prof. Bhandari and Dr. Bell are paid consultants of Ambu A/S. They have not been compensated for their quotes within this press release.

About Ambu

Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anaesthesia, and patient monitoring solutions. We continuously look to the future with a commitment to deliver innovative quality products that have a positive impact on patient care and the work of healthcare professionals. Headquartered near Copenhagen in Denmark, Ambu employs approximately 4,500 people in Europe, North America and the Asia Pacific.

For more information, please visit:

ambu.com or **ambuUSA.com**

MIRIKIZUMAB DEMONSTRATES SUPERIORITY OVER PLACEBO IN PHASE 3 MAINTENANCE STUDY IN ULCERATIVE COLITIS, SUPPORTING REGULATORY SUBMISSIONS IN 2022

Significantly more patients treated with Mirikizumab maintenance dosing achieved the primary endpoint of clinical remission at one year (52 weeks), and all key secondary endpoints were met

Mirikizumab is the first and only anti-IL23p19 to demonstrate maintenance of clinical remission in a Phase 3 study in UC

INDIANAPOLIS, Dec. 14, 2021 /PRNewswire/– Eli Lilly and Company (NYSE: LLY) announced that mirikizumab met the primary endpoint of clinical remission and all key secondary endpoints at one year in LUCENT-2, a Phase 3 maintenance study evaluating the efficacy and safety of mirikizumab for the treatment of patients with moderately-to-severely active ulcerative colitis (UC). Patients in this study were previously enrolled in a 12-week induction study, LUCENT-1. These results build on the positive outcomes from LUCENT-1.

In LUCENT-2, for patients who achieved clinical response with mirikizumab in the 12-week induction study and were re-randomized to mirikizumab maintenance dosing, a statistically higher proportion met the primary endpoint of clinical remission at one year compared to patients who were re-randomized to placebo ($p<0.001$). Clinical remission is reached when inflammation of the colon is controlled or resolved, leading to normalization or near-normalization of symptoms such as frequent and bloody stools. All key secondary endpoints were also met ($p<0.001$), including significantly higher proportions of patients treated with mirikizumab achieving endoscopic remission, corticosteroid-free remission, resolution or near-resolution of bowel urgency, improvement in endoscopic histologic intestinal inflammation and maintenance of remission, and greater reduction from baseline in bowel urgency symptoms at one year compared to placebo.

"In this maintenance study, treatment with mirikizumab demonstrated clinically meaningful and statistically significant improvements in clinical, endoscopic and histologic measures, including reduction of bowel urgency – a novel endpoint in the LUCENT program," said Bruce E. Sands, M.D., M.S., Dr. Burrill B. Crohn Professor

of Medicine, Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at the Icahn School of Medicine at Mount Sinai. "Bowel urgency is one of the most bothersome and disruptive symptoms people living with ulcerative colitis experience, and the LUCENT program leveraged an innovative and systematic patient-centric approach to assess patients' symptoms."

In the placebo-controlled maintenance cohort, the frequency of serious adverse events among patients treated with mirikizumab was numerically lower compared to placebo, and the overall safety profile was consistent with that of the previous mirikizumab studies in UC and other studies within the anti-IL-23p19 antibody class. The most common treatment emergent adverse events reported among patients treated with mirikizumab were nasopharyngitis, arthralgia and exacerbation of ulcerative colitis. Additional adverse events of interest reported among patients treated with mirikizumab included hypersensitivity, injection site reaction, depression, liver enzyme elevation, herpes zoster and oral candidiasis.

"Existing therapies aren't fully meeting the needs of people with ulcerative colitis who still have unresolved symptoms that impact their health and quality of life," said Lotus Mallbris, M.D., Ph.D., vice president of global immunology development and U.S. and global medical affairs at Lilly. "These positive long-term results provide evidence that mirikizumab has the potential to be an effective treatment option and become the first medicine of its kind for people with ulcerative colitis, including those who suffer from bowel urgency."

With these data, Lilly plans to submit a Biologics License Application (BLA) to the FDA for mirikizumab in UC, followed by submissions to other regulatory agencies around the world in the first half of 2022.

"The results announced today are encouraging for those who live with ulcerative colitis," said Michael Osso, President and CEO for Crohn's & Colitis Foundation. "We're excited about potential new options in the inflammatory bowel disease treatment space that may be able to help people living with ulcerative colitis successfully control their disease symptoms and achieve remission."

Topline results from the Phase 3 induction study, LUCENT-1, were announced in March 2021. Data from the Phase 3 LUCENT program, including results from LUCENT-1 and LUCENT-2, will be disclosed at upcoming congresses and in publications in 2022. Additional Phase 3 clinical trials are ongoing for mirikizumab in Crohn's disease.

About Mirikizumab

Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the p19 subunit of interleukin 23. Mirikizumab is being studied for the treatment of immune-mediated diseases, including ulcerative colitis and Crohn's disease.

About the LUCENT Clinical Trial Program

The LUCENT Phase 3 clinical development program for mirikizumab includes LUCENT-1, LUCENT-2 and LUCENT-3. LUCENT-1 (NCT03518086) is a multicenter, randomized, double-blind, placebo-controlled induction study of mirikizumab in patients with moderately-to-severely active ulcerative colitis who have previously failed conventional and/or biologic therapies and/or JAK inhibitors. LUCENT-2 (NCT03524092) is a multicenter, randomized, double-blind, placebo-controlled, Phase 3 maintenance study in patients who completed

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LUCENT-1. LUCENT-3 (NCT03519945) is an open label extension study for eligible patients who have participated in mirikizumab UC trials.

The program began in 2018, with full results from the induction and maintenance studies anticipated in early 2022.

About Ulcerative Colitis

Ulcerative colitis is a chronic inflammatory bowel disease that affects the colon.[1] UC occurs when the immune system sends white blood cells into the lining of the intestines, where they produce chronic inflammation and ulcerations.[2] There is an unmet need for additional treatment options for UC that provide meaningful symptom relief, including bowel urgency, and deliver sustained clinical remission. UC can cause significant and debilitating disruptions in daily life. Millions of people live with UC globally.[3]

About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism.

To learn more about Lilly, please visit us at:

lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about mirikizumab as a potential treatment for patients with ulcerative colitis and other diseases and reflects Lilly's current beliefs and expectations. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that mirikizumab will prove to be a safe and effective treatment or that mirikizumab will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

1. Overview of Ulcerative Colitis. Crohn's and Colitis Foundation Website. crohnscolitisfoundation.org/what-is-ulcerative-colitis/overview
2. What is Ulcerative Colitis? Crohn's and Colitis Foundation Website. crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/
3. Adelphi Data 2017.