LILLY'S MIRIKIZUMAB HELPS PATIENTS ACHIEVE CLINICAL REMISSION AND IMPROVES SYMPTOMS IN ADULTS WITH ULCERATIVE COLITIS IN 12-WEEK PHASE 3 INDUCTION STUDY

- ***Patients treated with mirikizumab met the primary endpoint of clinical remission and all key secondary endpoints compared to placebo***
- ***LUCENT-1 is the first and only Phase 3 study of an anti-IL-23p19 monoclonal antibody to demonstrate reduced bowel urgency in moderate to severe ulcerative colitis***
- ***Safety results in this study were consistent with that of the previous mirikizumab study in ulcerative colitis and studies with the anti-IL-23p19 antibody class***

INDIANAPOLIS, March, 2021 – Eli Lilly and Company (NYSE: LLY) announced that mirikizumab met the primary and all key secondary endpoints in LUCENT-1, a 12-week Phase 3 induction study evaluating the efficacy and safety of mirikizumab for the treatment of patients with moderate to severe ulcerative colitis (UC). LUCENT-2, a multicenter, randomized, double-blind, placebo-controlled maintenance study of mirikizumab in patients who have completed the 12-week LUCENT-1 induction study is ongoing.

UC is a chronic inflammatory disease of the large intestine, also referred to as the colon, that affects the lining of the colon and may cause small sores, or ulcers, to form. [i] This inflammation can cause abdominal pain, frequent and urgent trips to the bathroom, bloody stools and incontinence.[1] UC can cause significant and debilitating disruptions in daily life. Millions of people live with UC globally.[2]

"There is a continued need for additional treatments that can provide people living with ulcerative colitis relief from their most challenging symptoms," said William J. Sandborn, MD, Professor of Medicine, and Chief, Division of Gastroenterology, University of California San Diego. "Results of this study provide further clinical evidence of the potential for mirikizumab to become the first anti-IL-23p19 biologic for the treatment of ulcerative colitis."

In LUCENT-1, mirikizumab met the primary endpoint of clinical remission at Week 12 compared to placebo ($p<0.0001$). Clinical remission is met when inflammation of the colon is controlled or resolved, leading to normalization or near-normalization of symptoms such as stool frequency and bleeding.

Mirikizumab also achieved all key secondary endpoints compared to placebo at Week 12 in patients with UC with highly statistically significant p-values, including reduced bowel urgency, clinical response, endoscopic remission, symptomatic remission and improvement in endoscopic histologic inflammation. In addition, mirikizumab demonstrated rapid improvement in patient symptoms as early as four weeks after initiating treatment. Mirikizumab also reduced symptoms among patients who had previously not responded to or stopped responding to biologic and/or Janus kinase (JAK) inhibitor therapies.

In the 12-week placebo-controlled induction study of LUCENT-1, the incidence of treatment-emergent adverse events (AEs) and serious AEs among patients treated with mirikizumab was consistent with that of the previous Phase 2 mirikizumab study in UC and studies with the anti-IL-23p19 antibody class. The most common AEs included nasopharyngitis, anemia and headache for both placebo and mirikizumab-treated patients.

"People living with UC often struggle to effectively manage recurring flare ups of the disease," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "With these positive results, we look forward to the continuation of the maintenance study through 52 weeks in hopes of providing a new option to people living with UC."

The full LUCENT study results, including data from LUCENT-2 and LUCENT-3, will be disclosed at a future congress or publication.

"Ulcerative colitis can be debilitating and unpredictable for the hundreds of thousands of people living with this chronic disease," said Dr. Caren Heller, Chief Scientific Officer for the Crohn's & Colitis Foundation. "We're encouraged by these promising results for a potential new treatment that may help provide symptom relief and remission."

About Mirikizumab

Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the p19 subunit of interleukin

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23. Mirikizumab is being studied for the treatment of immune diseases, including psoriasis, 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, Phase 3 induction study of mirikizumab in patients with moderate to severe UC who had failed conventional and/or biologic treatments. LUCENT-2 (NCT03524092) is a multicenter, randomized, double-blind, placebo-controlled maintenance study of mirikizumab in patients who have completed the 12-week LUCENT-1 induction study. 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.[3] There is an unmet need for additional treatment options for UC that provide meaningful symptom relief, including bowel urgency, and deliver sustained clinical remission.

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**

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 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.https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/overview. Accessed February 2021.
2. Adelphi Data 2017.
3. What is Ulcerative Colitis? Crohn's and Colitis Foundation Website. http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/. Accessed February 2021.

CELLMAX LIFE AND SEBELA PHARMACEUTICALS ENTER STRATEGIC DEVELOPMENT AND COMMERCIALIZATION PARTNERSHIP FOR FIRSTSIGHT™ BLOOD TEST FOR DETECTION OF COLORECTAL CANCER AND PRE-CANCER

CellMax Life closes Series C financing to accelerate development and regulatory approvals of FirstSight

SUNNYVALE, CA and ROSWELL, GA (March, 2021) – CellMax Life, a molecular diagnostics company with proprietary technology for pre-cancer and cancer detection blood tests, and Sebela Pharmaceuticals, a market leader in gastroenterology, announce the closing of a strategic development and commercial collaboration agreement, as well as CellMax's Series C financing. Participation in the financing also includes a strategic investment from new investor, Aflac Ventures, the corporate venture arm of Aflac Incorporated (NYSE: AFL), and existing

investor, ArtimanVentures.

"Strategic financing from market leaders, Sebela and Aflac Ventures, is a testament to CellMax's technology and vision," said Atul Sharan, chief executive officer, CellMax Life. "Sebela has a leading market position in the gastroenterology field in the United States. The financing will bring to life our vision of detecting colon cancer before it occurs through a globally marketed blood test that can detect pre-cancerous polyps."

The Series C financing will be used to accelerate the clinical development of CellMax's multimodal liquid biopsy test, FirstSight™, for the detection of colorectal cancer and pre-cancerous polyps, also known as advanced adenomas. CellMax recently initiated a multicenter U.S. study to further optimize its proprietary algorithm and cell capture techniques. CellMax and Sebela will collaborate on completing the development of FirstSight and, following approval from the U.S. Food and Drug Administration, Sebela will commercialize the test in the United States.

"For the last several years, we have closely followed the industry's development of colorectal cancer liquid biopsies," said Alan Cooke, chief executive officer, Sebela Pharmaceuticals. "Sebela and our subsidiary, Braintree, have worked with gastroenterologists for over 35 years, and we expect FirstSight to play a central role in the future of colorectal cancer screening. FirstSight may not only enable the U.S. to exceed its 80% screening rate target, as set by the National Colorectal Cancer Roundtable, but can also help detect pre-cancerous adenomas early, referring patients to colonoscopy for preemptive removal."

This partnership complements Sebela's portfolio of market-leading gastroenterology and colonoscopy preparation products, which are utilized to facilitate colonoscopies, the "gold standard" for the prevention and detection of colorectal cancer. Colonoscopies remain the only means of removing detected pre-cancerous lesions to prevent colorectal cancer.

At the 2021 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancer Symposium, Dr. Shai Friedland, professor of medicine at Stanford University Medical Center and chief of gastroenterology at the VA Palo Alto Health Care System, presented results from a prospective study performed on 458 subjects utilizing FirstSight, a multimodal assay comprised of circulating dysplastic epithelial cells and circulating tumor DNA mutation markers, in combination with a proprietary algorithm.

"A test that detects only colorectal cancer, and not adenomas, will result in missed opportunities to prevent cancer and subject patients to invasive cancer treatments," said Dr. Friedland. "Today, there is not a single non-invasive screening test that can accurately detect pre-cancerous polyps even nearly as effective as a colonoscopy. Our study data with the FirstSight blood test continues to show consistent ability to detect advanced adenomas with high sensitivity, enabling removal before they progress to carcinomas."

In clinical studies performed in the U.S. and Taiwan, FirstSight has demonstrated strong performance in detecting both advanced adenomas and colorectal cancer. FirstSight has also shown the ability to detect recurrent neoplasia following polypectomy. i-v [i], [ii], [iii], [iv], [v]

Colorectal cancer represents the second deadliest cancer in the U.S., despite being one of the most preventable.[vi] Additionally, screening adherence rates have fallen short of the 80% target, as only 68.8% of adults aged 50 to 75 years, and only 63.3% of adults aged 50 to 64 years, were up to date with colorectal cancer screening as of 2018.[vii]

About CellMax Life

CellMax Life is a diagnostics company focused on cancer screening with proprietary technology for detecting precancerous and cancer cells and genomic aberrations in a single blood sample. CellMax Life is headquartered in Sunnyvale, California, and has a CLIA certified and CAP accredited laboratory at this location.

For more information, visit:
cellmaxlife.com

About Sebela Pharmaceuticals®

Sebela Pharmaceuticals is a growth-oriented pharmaceutical company focused in gastroenterology, colorectal cancer detection and prevention. Braintree, a part of Sebela Pharmaceuticals, is a pioneer in colonoscopy

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screening with a broad marketed portfolio of innovative prescription colonoscopy preparations and gastroenterology products. Braintree has multiple clinical development programs including, in collaboration with Cellmax Life, a multimodal liquid biopsy test, FirstSight™, for the detection of colorectal cancer and pre-cancerous polyps. Sebela's core therapeutic areas also include women's health and dermatology. In women's health, Sebela has two next generation intra-uterine devices (IUDs) for contraception in late-stage clinical development. Sebela Pharmaceuticals has offices in Roswell, GA; Braintree, MA; and Dublin, Ireland; has annual net sales of $200-250 million; and has grown to over 300 employees through strategic acquisitions and organic growth. Please visit sebelapharma.com for more information.

About Aflac Incorporated

Aflac Incorporated (NYSE: AFL) is a Fortune 500 company helping provide protection to more than 50 million people through its subsidiaries in Japan and the U.S., where it is a leading supplemental insurer by paying cash fast when policyholders get sick or injured. For more than six decades, insurance policies of Aflac Incorporated's subsidiaries have given policyholders the opportunity to focus on recovery, not financial stress. Aflac Life Insurance Japan is the leading provider of medical and cancer insurance in Japan where it insures 1 in 4 households. For 15 consecutive years, Aflac Incorporated has been recognized by Ethisphere as one of the World's Most Ethical Companies. In 2021, Fortune included Aflac Incorporated on its list of World's Most Admired Companies for the 20th time, and Bloomberg added Aflac Incorporated to its Gender-Equality Index, which tracks the financial performance of public companies committed to supporting gender equality through policy development, representation and transparency, for the second consecutive year.

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Forward Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sebela Pharmaceuticals under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the development, launch, introduction and commercial potential of FirstSight™; growth and opportunity, including peak sales and the potential demand for FirstSight™, as well as its potential impact on applicable markets; market size; substantial competition; our ability to continue as a growing concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third-party payer reimbursement; dependence upon third parties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and risks related to failure to obtain FDA and/or CMS clearances or approvals and noncompliance with FDA regulations. As with any diagnostic under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Sebela Pharmaceuticals does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.