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Sebela Pharmaceuticals® Announces Successful Completion of Phase 3 TRIUMpH Program of Tegoprazan in GERD with Positive 24-Week Maintenance Phase Results

- Tegoprazan demonstrated statistically superior maintenance of healing in all patients across all grades (LA Grades A–D) of erosive esophagitis (EE) and in the most severe patients (LA Grades C/D) versus lansoprazole 15mg.
- Safety and tolerability continued to be similar to lansoprazole and mean serum gastrin levels remained within normal limits throughout the maintenance phase (<180 Ng/L).
- New Drug Application (NDA) to be filed with FDA for both EE and NERD in Q4 2025.

BRAINTREE, Mass., August 7, 2025 /PRNewswire/ – Braintree Laboratories, a part of Sebela Pharmaceuticals® and a leading manufacturer of gastroenterology pharmaceutical products, today announced positive topline results from the 24-week maintenance phase of the pivotal Phase 3 TRIUMpH clinical program evaluating tegoprazan, a novel potassium-competitive acid blocker (P-CAB), in gastroesophageal reflux disease (GERD).

Following an initial healing phase of up to 8 weeks, patients with EE who achieved complete healing were randomized to maintenance treatment with tegoprazan 100mg, tegoprazan 50mg, or lansoprazole 15mg for 24 weeks. The study met its primary endpoint, with both tegoprazan doses achieving non-inferiority to lansoprazole for the percentage of all patients (LA Grades A–D) with sustained healing at 24 weeks. Notably, both tegoprazan 100mg and 50mg were also statistically superior to lansoprazole 15mg for maintenance of healing in this population.

In the most severe EE patients (LA Grade C/D), both doses demonstrated meaningful improvement over lansoprazole 15mg for maintenance of healing at 24 weeks, with tegoprazan 100mg showing statistical superiority. Both tegoprazan doses also achieved non-inferiority versus lansoprazole in the proportion of 24-hour heartburn-free days over the study period, similar to what was achieved in the previously reported 8-week phase 3 studies in EE healing. In the 4-week NERD trial, both doses of tegoprazan demonstrated superiority over placebo for heartburn, regurgitation and overnight heartburn, the cardinal symptoms of GERD.

The safety profile was favorable, with low rates of treatment-emergent adverse events (TEAEs) and adverse events of special interest (AESIs). No new safety signals were identified. Mean serum gastrin

levels remained below the upper limit of normal (<180 Ng/L) at all timepoints for both tegoprazan doses.

Earlier this year, Sebela Pharmaceuticals announced positive top-line GERD results for tegoprazan in NERD as well as the healing phase of the TRIUMpH EE study where it achieved statistically significant results across all endpoints related to EE healing and symptom resolution.

Sebela Pharmaceuticals plans to file both EE and NERD indications with FDA in Q4 2025. Results from the TRIUMpH Phase 3 studies will be submitted to high impact, peer reviewed journals along with presentation of this data at leading gastroenterology conferences in the future.

“These results reinforce the potential of tegoprazan to redefine long-term management of GERD,” said Alan Cooke, President and CEO of Sebela Pharmaceuticals. “We are excited that tegoprazan not only delivers superior and sustained healing across the full spectrum of erosive esophagitis, including more challenging severe cases, but also provides durable control of heartburn with a safety profile comparable to existing therapies. We look forward to advancing tegoprazan in the U.S. to better serve the needs of patients living with GERD.”

Dr. Prakash Gyawali, Professor of Medicine and Director of the Neurogastroenterology and Motility Program at Washington University®, added, “These maintenance data establish the sustained clinical value of tegoprazan in GERD, even in the most severe categories of erosive esophagitis. Overall, these findings support the promise of tegoprazan as an important new tool to improve lives of GERD patients by providing healing and symptom relief.”

Individual treatment-emergent adverse events (TEAEs) occurred at a rate of ≤ 3% in the TRIUMpH studies and were generally mild and transient. Individual serious TEAEs occurred at a rate of < 1%. The rates of TEAEs and serious TEAEs in each study were similar between tegoprazan and the PPI and placebo comparator groups. Mean serum gastrin levels for tegoprazan and lansoprazole remained within the normal range (0-180 pg/ml) throughout the relevant treatment periods in both TRIUMpH studies.

About TRIUMpH

The TRIUMpH program comprises two Phase 3 studies of tegoprazan in US patients with gastroesophageal reflux disease (GERD), including erosive esophagitis (EE) and non-erosive reflux disease (NERD). The Phase 3 studies were conducted entirely in the US and are representative of the demographically diverse US population.

The Phase 3 EE study (NCT05587309) consisted of a large, multi-center, double-blind study (n=1,250, including 463 patients with LA Grade C/D esophagitis) evaluating the safety and efficacy of tegoprazan versus lansoprazole for indications including the healing of all grades of EE, maintenance of EE healing and relief of heartburn. Patients were treated in the EE Healing Phase for up to 8 weeks. The primary endpoint in the Healing Phase was the proportion of patients with complete endoscopic healing by the week 8 visit. Patients with healed EE then participated in a 24

Maintenance Phase. The primary endpoint of the Maintenance Phase was the proportion of patients who maintained complete endoscopic healing at the week 24 visit. The percentage of 24-hour heartburn-free days was evaluated as a secondary endpoint in both the Healing and Maintenance Phases.

The Phase 3 NERD study (NCT05587322) consisted of a large, multicenter, double-blind study (n=800) designed to demonstrate the safety and efficacy of tegoprazan versus placebo. The primary endpoint for the placebo-controlled treatment phase was the percentage of 24-hour heartburn-free days. Additional key endpoints included percentage of days without overnight heartburn and percentage of days without regurgitation.

About Tegoprazan

Tegoprazan is a novel agent in phase 3 development for the treatment of acid-related gastrointestinal diseases. It is a member of a class of oral medications known as P-CABs, or potassium-competitive acid blockers, which have been shown to have rapid onset of action, the ability to control gastric pH for longer periods of time than proton pump inhibitors (PPIs) and superior efficacy in sustained healing of EE, including in the most severe EE patients. Tegoprazan has already received marketing authorization in 21 countries.

About GERD

GERD is a chronic and highly prevalent disorder affecting approximately 65 million people in the US. It is characterized by a wide variety of symptoms, including heartburn and acid regurgitation. The main phenotypic presentations of GERD include non-erosive reflux disease (NERD) and erosive esophagitis (EE). NERD is defined by reflux-related symptoms without esophageal erosions. In addition to reflux-related symptoms, EE is defined by erosions in the esophagus caused by acid reflux from the stomach. While proton pump inhibitors are the mainstay of therapy for both EE and NERD, 35% to 54% of patients fail to achieve complete relief of symptoms[1], highlighting a significant unmet need in this population.

About Sebela Pharmaceuticals®

Sebela Pharmaceuticals is a US pharmaceutical company with a market leading position in gastroenterology and a focus on innovation in women's health. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, has been the market leader in colonoscopy screening preparations for over 40 years, having invented, developed and commercialized a broad portfolio of innovative prescription colonoscopy preparations and multiple gastroenterology products. Braintree also has a pipeline of gastroenterology late-stage clinical development programs, including tegoprazan, a novel agent in phase 3 development for the treatment of acid-related gastrointestinal diseases. In addition, Sebela Women's Health recently obtained FDA approval for Miudella®, the first non-hormonal intra-uterine

[1] Chey WD, Mody RR, Izat E. Patient and physician satisfaction with proton pump inhibitors (PPIs): are there opportunities for improvement? Dig Dis Sci. 2010

device (IUD) for contraception to be approved in over 40 years. Sebela Pharmaceuticals also has LevoCept®, a hormonal IUD, in late-stage development.

Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland; annual net sales of approximately $100 million; and about 250 employees.

Please visit **sebelapharma.com** for more information or call 800-874-6756.

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® and Braintree Laboratories 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 tegoprazan; growth and opportunity, including peak sales and the potential demand for tegoprazan, 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 clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical 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 neither Sebela Pharmaceuticals nor Braintree Laboratories agree to undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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