FOR IMMEDIATE RELEASE

Sebela Pharmaceuticals Presents Phase 3 Tegoprazan Data in Erosive Esophagitis at Digestive Disease Week® (DDW) 2026

Key Highlights:

- *Two oral presentations at DDW 2026 built upon previously reported topline results from the TRIUMpH-EE Phase 3 trials for tegoprazan and covered both erosive esophagitis (EE) healing and maintenance.*
- *These presentations highlight tegoprazan's superiority to a PPI, lansoprazole, in healing all grades of EE at weeks 2 and 8, in maintenance of healing at 24 weeks, and in relieving heartburn symptoms in the most severe patients (LA Grade C/D) at weeks 8 and 24.*

BRAINTREE, Mass., May 5, 2026 – Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals and a leading manufacturer of gastroenterology pharmaceutical products, today announced that positive results from the Phase 3 TRIUMpH-EE clinical program evaluating tegoprazan were presented in two oral abstract sessions at DDW 2026. Tegoprazan is a novel, fast acting, potassium-competitive acid blocker (P-CAB), with a self-regulating mechanism of action, developed for the healing and maintenance of healing of erosive esophagitis (EE) and for the relief of heartburn associated with non-erosive reflux disease (NERD).

The TRIUMpH-EE program was conducted entirely in the United States and enrolled 1,245 adults with EE, including 463 patients with severe disease (Los Angeles (LA) Grade C/D), to evaluate tegoprazan versus the proton pump inhibitor (PPI) lansoprazole for both acute healing and 24-week maintenance of healing. As previously reported, tegoprazan met all primary and secondary endpoints in the healing phase and demonstrated statistically superior healing at Weeks 2 and 8 across all LA grades and in patients with severe EE. Additionally, tegoprazan showed superior sustained healing over 24 weeks compared with lansoprazole in the maintenance phase across all LA grades of EE, with greater therapeutic differences observed in patients with severe EE (LA Grade C/D). Once-daily dose of 100 mg of tegoprazan was also effective in reducing 24-hour heart-burn free days and statistically superior in patients with severe EE (LA Grade C/D).

"These oral presentations at DDW provided the GI community with the first in-depth look at our Phase 3 erosive esophagitis data for tegoprazan," said Alan Cooke, President and Chief Executive Officer of Sebela Pharmaceuticals. "Across the TRIUMpH program, tegoprazan has demonstrated the potential to deliver faster and more complete healing, sustained maintenance of healing, and meaningful relief of heartburn and regurgitation in patients

with GERD, including those with more severe disease who often remain symptomatic despite conventional PPI therapy. These positive results are directly related to the self-regulating mechanism of action of tegoprazan which differentiates it from other products on the market."

DDW 2026 TRIUMpH-EE Oral Presentations

Erosive Esophagitis Healing
Presenter: Felice Schnoll-Sussman, MD (Weill Cornell Medicine)
Session Title: Clinical Advances in GERD
Session Date & Time: May 4, 2026, 8:00–9:30 AM CDT
Presentation Title: TEGOPRAZAN 100MG DEMONSTRATES SUPERIOR AND FASTER HEALING OF EROSIVE ESOPHAGITIS AND HEARTBURN RELIEF VERSUS LANSOPRAZOLE: RESULTS FROM THE PHASE 3 TRIUMPH STUDY

This presentation reported detailed results from the 8-week healing phase of TRIUMpH-EE, a randomized, double-blind, multicenter study comparing tegoprazan 100 mg once daily with lansoprazole 30 mg once daily in adults with EE (LA Grades A–D). The primary endpoint was the proportion of patients with complete endoscopic healing at Week 8, evaluated for non-inferiority, with a prespecified hierarchical testing strategy for key secondary endpoints including Week 2 and Week 8 healing superiority and 24-hour heartburn-free days.

Key results:

- *Proportion of patients with complete healing at Week 8: tegoprazan [84.6%] vs lansoprazole [78.0%] (Δ=6.6%); non-inferiority achieved and superiority achieved; (p=0.0083).*
- *Proportion of patients with complete healing at Week 2: tegoprazan [76.4%] vs lansoprazole [67.0%] (Δ=9.4%); superiority achieved (p<0.0001).*
- *Healing outcomes in patients with severe EE (LA Grade C/D) at Weeks 2 and 8: Week 2: tegoprazan [74.1%] vs lansoprazole [54.5%] (Δ=19.6%); superiority achieved (p<0.0001); Week 8: tegoprazan [83.2%] vs lansoprazole [68.0%] (Δ=15.2%); superiority achieved (p=0.0002).*
- *Percentage of 24-hour heartburn-free days through Week 8: tegoprazan [54.3%] vs lansoprazole [51.9%] (p<0.0001 for non-inferiority). In patients with severe EE (LA Grade C/D): tegoprazan [60.1%] vs lansoprazole [53.6%] (Δ=6.5%); superiority achieved (p=0.0289).*

- *Tegoprazan 100mg was shown to be safe for the healing of EE, with no differences in treatment emergent adverse events (TEAEs) or adverse events of special interest (AESIs) versus lansoprazole 30mg. Mean serum gastrin levels remained within normal limits throughout the study.*

Erosive Esophagitis Maintenance of Healing

Presenter: C. Prakash Gyawali, MD (Washington University School of Medicine)
Session Title: GERD Quickshots: What's New From Presentation to Management
Session Date & Time: May 5, 2026, 8:00–9:30 AM CDT
Presentation Title: TEGOPRAZAN PROVIDES SUPERIOR 24-WEEK MAINTENANCE OF HEALING AND CONTROL OF HEARTBURN SYMPTOMS IN PATIENTS WITH EROSIVE ESOPHAGITIS: RESULTS FROM THE PHASE 3 TRIUMPH STUDY

This presentation highlighted the 24-week maintenance data from TRIUMpH-EE in patients who achieved complete endoscopic healing after up to 8 weeks of treatment and were re-randomized to receive tegoprazan 100 mg, tegoprazan 50 mg, or lansoprazole 15 mg once daily. The primary endpoint was the proportion of patients with sustained complete healing at Week 24; secondary endpoints included 24-hour heartburn-free days and outcomes in patients with severe EE. All key secondary endpoints were tested in a prespecified hierarchical manner.

Key results:

- *Proportion of patients with sustained complete healing at Week 24 (all LA grades): tegoprazan 100 mg [69.4%], tegoprazan 50 mg [61.4%], lansoprazole 15 mg [50.6%] (Δs=18.8% & 10.8%, respectively) (non-inferiority achieved; superiority achieved vs lansoprazole: 100 mg p<0.0001, 50 mg p=0.0145).*
- *Sustained healing at Week 24 in patients with LA Grade C/D: tegoprazan 100 mg [76.4%] vs lansoprazole 15 mg [44.3%] (Δ=32.1%); superiority achieved (p<0.0001); tegoprazan 50 mg [57.9%] (Δ=13.6%) (p=0.061 for superiority).*
- *Percentage of 24-hour heartburn-free days at 24 weeks for tegoprazan 100mg [72.9%] and 50mg [69.9%] versus lansoprazole [69.4%] (Δs=3.5% & 0.5%, respectively) (p<0.0001 for non-inferiority). In patients with severe EE (LA Grade C/D); tegoprazan 100mg [84.2%] vs lansoprazole [70.4%], superiority achieved (p=0.0018) (Δ=13.8%).*

- *Rates of TEAEs and AESIs were low for both doses of tegoprazan and comparable to lansoprazole with no dose effect. Mean serum gastrin levels remained within the normal range for the duration of treatment.*

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers, and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE), and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 2 to May 5, 2026. Additional information can be found at ddw.org.

About the TRIUMpH Program

The TRIUMpH clinical program comprises two pivotal Phase 3 studies of tegoprazan in US patients with gastroesophageal reflux disease (GERD), including an erosive esophagitis (TRIUMpH-EE; NCT05587309) study and a non-erosive reflux disease (TRIUMpH-NERD; NCT05587322) study. TRIUMpH-EE evaluated the healing and maintenance of healing of EE and the relief of heartburn, while TRIUMpH-NERD evaluated tegoprazan 50 mg and 100 mg vs placebo in patients with NERD. Sebela expects to submit data from TRIUMpH-NERD for presentation at the American College of Gastroenterology (ACG) 2026 Annual Scientific Meeting.

Across the TRIUMpH program, individual treatment-emergent adverse events occurred at a rate of approximately 3% and were generally mild and transient, and serious events occurred at approximately 2% with similar rates between tegoprazan and active or placebo comparators. Mean serum gastrin levels for tegoprazan and lansoprazole remained within the normal range (0–180 pg/mL) throughout the treatment periods.

About Tegoprazan

Tegoprazan is a novel, fast acting, once-daily, oral potassium-competitive acid blocker (P-CAB) with a self-regulating mechanism of action, in development in the United States for the treatment of adults with gastroesophageal reflux disease (GERD). P-CABs provide rapid, reversible, potassium-competitive inhibition of the gastric proton pump and have been shown to provide faster onset and sustained control of gastric acidity compared to proton pump inhibitors (PPIs). In Phase 1 pharmacodynamic studies, tegoprazan demonstrated rapid acid control, achieving an intragastric pH above 4 within 45 minutes of

dosing. Tegoprazan has received marketing authorization in 23 countries worldwide and is marketed as K-CAB® in several regions outside the United States, including South Korea.

In January 2026, Sebela submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of tegoprazan for the treatment of heartburn associated with non-erosive reflux disease (NERD), the healing of EE, and the maintenance of healing of EE in adults. US approval is anticipated in January 2027.

About GERD and Erosive Esophagitis

GERD is a chronic, highly prevalent gastrointestinal disorder affecting approximately 65 million people in the United States and characterized by symptoms such as heartburn and acid regurgitation.[1] EE is a phenotype of GERD in which reflux of gastric contents leads to visible erosions in the esophageal mucosa, and patients with severe EE (LA Grade C/D) are at increased risk of complications and often require long-term maintenance therapy. PPIs have been the mainstay of GERD therapy for decades, yet 35–54% of patients experience incomplete symptom relief, highlighting a significant unmet need.[2,3]

About Sebela Pharmaceuticals

At Sebela Pharmaceuticals, we are building a leading gastroenterology company in the US and developing innovative products in women's health. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, has been innovating, developing, manufacturing, and commercializing gastroenterology products for over 40 years. Tegoprazan is Braintree's lead program in GERD, and in 2025 Sebela Women's Health obtained FDA approval for Miudella (copper-containing intrauterine system), the first non-hormonal intra-uterine device (IUD) for contraception approved in over 40 years. Sebela Pharmaceuticals has operations in Roswell, GA; Braintree, MA; and Dublin, Ireland.

For more information, visit www.sebelapharma.com.

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," "may", "will", "forecast," "estimated," "expected," and "intend," among others. There are several 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, risks related to obtaining

FDA approval of tegoprazan; 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 going 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 the NDA discussed in this press release will be approved 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 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.

References:

[1]*El-Serag HB, et al. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. Gut. 2014.*

[2]*Chey WD, et al. Patient and physician satisfaction with proton pump inhibitors (PPIs): are there opportunities for improvement? Dig Dis Sci. 2010.*

[3]*Armstrong D, et al. Symptom Profile, Proton Pump Inhibitor Therapy, and Diagnostic Testing in Patients with Persistent Reflux-Like Symptoms: Results from a Population-Based Survey. Foregut. 2023.*

Media Contact:
Sebela Pharmaceuticals Inc.
Email: **info@sebelapharma.com**
Phone: +1 844 SEBELA1
Website: **www.sebelapharma.com**

950-1057-v1