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Sebela Pharmaceuticals to Present Positive Phase 3 Tegoprazan Data in Non-Erosive Reflux Disease (NERD) at the American College of Gastroenterology (ACG) 2026 Meeting

Key Highlights:

- ***Tegoprazan is the first and only P-CAB reported to demonstrate clinical improvement in both hallmark symptoms of NERD, heartburn and regurgitation, in a prospective U.S. phase 3 clinical trial.***
- ***Detailed analysis from the randomized, double-blind, placebo-controlled Phase 3 TRIUMpH-NERD study demonstrated that both doses of tegoprazan produced statistically significant improvements in the percentage of 24-hour heartburn free days and days without nighttime heartburn versus placebo through week 4.***
- ***Prespecified analyses also showed greater percentages of days without regurgitation and without both heartburn and regurgitation with tegoprazan versus placebo.***
- ***Tegoprazan demonstrated treatment effect from Day 1 and continued improvement in heartburn-free days through the 20-week extension period.***
- ***A separate ACG Presidential Award recognized post hoc analysis of the TRIUMpH erosive esophagitis (EE) program applied Lyon 2.0 Consensus criteria and found superior EE healing and maintenance of healing with tegoprazan compared to lansoprazole among patients with conclusive GERD.***

BRAINTREE, Mass., October 11, 2026 – Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, with a 40-year commitment to gastroenterology, today announced (1) positive results from the Phase 3 TRIUMpH clinical program evaluating tegoprazan in adults with non-erosive reflux disease (NERD) and (2) an American College of Gastroenterology (ACG) Presidential Award recognized post hoc analysis of TRIUMpH EE data at the ACG 2026 Annual Scientific Meeting.

“Together, these NERD and EE analyses strengthen the evidence for tegoprazan across major GERD phenotypes and address persistent treatment gaps,” said **Alan Cooke, President and Chief Executive Officer of Sebela Pharmaceuticals**. “These findings represent important progress toward our vision of advancing the treatment of GERD. We are committed to translating meaningful scientific advances into treatments that can make a difference for the millions of patients who still struggle with this disease.”

ACG 2026 TRIUMpH-NERD Oral Presentation

NERD is a common form of gastroesophageal reflux disease (GERD) in which patients experience reflux symptoms without visible erosive damage to the esophagus. Despite currently available therapies, many patients continue to experience persistent heartburn, regurgitation, or both, creating an unmet need for treatments that provide rapid and comprehensive relief.

Tegoprazan is an investigational, fast-acting potassium-competitive acid blocker (P-CAB) under development by Braintree Laboratories, Inc. for the treatment of GERD. The Phase 3 TRIUMpH program evaluated tegoprazan in diverse U.S. patient populations with both NERD and erosive esophagitis (EE). TRIUMpH-NERD (NCT05587322) was a randomized, double-blind, placebo-controlled, multicenter study that enrolled 783 adults with symptomatic NERD. Patients received tegoprazan 50mg, tegoprazan 100mg, or placebo once daily for four weeks, followed by a 20-week extension phase. The primary endpoint was the percentage of 24-hour heartburn-free days through Week 4, with the percentage of days without nighttime heartburn through Week 4 as a key secondary endpoint. Regurgitation was assessed as a prespecified exploratory endpoint.

Both doses of tegoprazan met the primary and secondary endpoints in the TRIUMpH-NERD study, despite enrolling a population with a high baseline disease burden. The detailed results presented at ACG demonstrated significant improvements in both 24-hour heartburn-free days and nighttime heartburn compared with placebo. Tegoprazan also significantly increased the percentage of days without regurgitation and the percentage of days free of both heartburn and regurgitation. The mean baseline heartburn severity was notable in this study with only 6.2% of patients having 24-hour heartburn free days at baseline. By comparison, in other NERD studies across PPIs and PCABs mean baseline heartburn severity was typically less severe with 12.9% to 22.6% of patients having 24-hour heartburn free days at baseline.^{1,2}

“For patients with NERD, meaningful treatment benefit requires addressing both heartburn and regurgitation, two symptoms that can substantially affect daily life,” said **Ronnie Fass, MD, Case Western Reserve University School of Medicine**, presenting author of the study. “In this study, tegoprazan demonstrated statistically significant improvements across heartburn, regurgitation, and the combined symptom-free endpoint.”

Key results:

- *Least-squares (LS) mean 24-hour heartburn-free days through Week 4 were 17.3% with placebo, 26.2% with tegoprazan 50 mg, and 30.1% with tegoprazan*

100 mg ($p=0.0006$ and $p<0.0001$, respectively), corresponding to relative increases of 51% and 74% over placebo.

- Improvements in 24-hour heartburn-free days continued to increase over 4 weeks, with rates of 38.9% for tegoprazan 50mg and 45.6% for tegoprazan 100mg compared to placebo of 26.7% measured at Day 28.
- LS mean days without nighttime heartburn were 27.0%, 36.1%, and 39.9%, respectively (50 mg vs placebo, $p=0.0017$; 100 mg vs placebo, $p<0.0001$).
- Treatment differences were apparent from Day 1, for heartburn-free days and days without regurgitation, supporting rapid onset of symptom improvement.
- During the open label extension phase of 20 weeks, the LS mean 24-hour heartburn-free days averaged 48% with tegoprazan 50mg and 50% with tegoprazan 100mg. Similar results were also seen in the extension phase for percentage of days without regurgitation.

For the combined endpoint of days free of both heartburn and regurgitation, tegoprazan demonstrated relative improvements of 60% and 76% over placebo for the 50mg and 100mg doses, respectively through Week 4. Improvement in both heartburn and regurgitation may be particularly meaningful for patients with NERD, as patients report both as the most common recurring symptoms of GERD. In a recent survey among 500 GERD patients, regurgitation was cited as the most common symptom overall, and the primary complaint by 83% of patients who are or have been treated with a PPI.³

ACG 2026 TRIUMpH-EE Presidential Award Abstract

A separate ACG Presidential Award-winning post hoc analysis of the TRIUMpH-EE (NCT05587309) data was presented by Dr. Walter Chan of Harvard Medical School. In this analysis, baseline EE was reclassified using Lyon Consensus 2.0: LA Grades B-D as conclusive GERD and LA Grade A as inconclusive GERD. In this study, endoscopies were scored by local readers and then subsequently evaluated by blinded central readers using comprehensive procedural videos. Patients ($n = 415$) with conclusive GERD taking 100 mg tegoprazan daily demonstrated statistically superior healing at Weeks 2 and 8 and maintenance of healing at Week 24 versus lansoprazole ($n = 399$). Tegoprazan 50 mg was also confirmed to be superior to lansoprazole at maintenance week 24. No statistically significant differences were observed between groups for inconclusive GERD.

Key results:

- In the modified intention-to-treat (m-ITT) population of 1,245 patients, rates of healed EE were higher with tegoprazan compared to lansoprazole among those with conclusive GERD per Lyon 2.0 (LA grades B-D) at week 2 (75.4% vs 60.7%, $p<0.0001$) and cumulatively by week 8 (83.4% vs 72.7%, $p=0.0005$), while no

statistically significant between-group differences were observed for inconclusive GERD (LA grade A).

- *Similar results were found in the per protocol (PP) analyses. Both tegoprazan 50mg and 100mg were superior to lansoprazole for maintenance of healing at 24 weeks for conclusive GERD in both the m-ITT ($p \leq 0.0019$) and PP analyses ($p < 0.0001$), while no differences were seen in inconclusive GERD.*

C. Prakash Gyawali, MD, Washington University School of Medicine, primary author of the Lyon 2.0 consensus and senior author of the abstract said, “The Lyon Consensus has established a standardized framework for objectively diagnosing GERD with confidence. These findings support the hypothesis that P-CABs are superior for patients with conclusive GERD and suggest that objective disease classification will help identify patients who may benefit most from treatment.”

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 vs lansoprazole, while TRIUMpH-NERD evaluated tegoprazan 50mg and 100mg vs placebo in patients with NERD.

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 pH dependent pharmacology, in development in the United States for the treatment of adults with gastroesophageal reflux disease (GERD). P-CABs reversibly inhibit the gastric proton pump through potassium-competitive binding. 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 24 countries worldwide and is marketed as K-CAB® in several regions outside the United States, including South Korea.

In January 2026, Braintree Laboratories, a part of Sebel, 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 regurgitation.⁴ 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.^{5,6}

About Sebel Pharmaceuticals

Sebel Pharmaceuticals is building a leading gastroenterology company dedicated to improving the lives of patients. Braintree Laboratories, Inc., a part of Sebel Pharmaceuticals, a trusted name in gastroenterology for more than 40 years, bringing deep expertise in the development, manufacturing, and commercialization of GI therapies. Sebel has demonstrated a strong track record of pharmaceutical innovation and regulatory execution, securing four FDA approvals over the past six years. Building on this foundation, the company is focused on advancing innovative therapies that address significant unmet needs in gastroenterology. Tegoprazan is Braintree's lead program. An NDA has been submitted based on the successful phase 3 TRIUMpH clinical program, and plans are underway for launch as a treatment for GERD. Sebel Pharmaceuticals has operations in 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 Sebel 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.

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References:

¹Laine L, et al. *Vonoprazan is Efficacious for Treatment of Heartburn in Non-erosive Reflux Disease: A Randomized Trial.* CGH. 2024.

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⁵Chey WD, et al. *Patient and physician satisfaction with proton pump inhibitors (PPIs): are there opportunities for improvement?* Dig Dis Sci. 2010.

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950-1066-v1