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**Sebela Pharmaceuticals® Announces Submission of New Drug Application to FDA for Tegoprazan for the Treatment of Gastroesophageal Reflux Disease**

Key Highlights:

- Sebela Pharmaceuticals® submitted its New Drug Application (NDA) for tegoprazan on January 9, 2026. The NDA seeks approval for three indications: Non-Erosive Reflux Disease (NERD), Erosive Esophagitis (EE) Healing, and EE Maintenance
    - Once approved, tegoprazan will be the first Potassium-Competitive Acid Blocker (P-CAB) to demonstrate superiority in EE healing across all severity grades (LA Grades A-D) and at all time points versus a proton pump inhibitor (PPI)
    - In NERD, tegoprazan achieved meaningful improvement in 24-hour heartburn, overnight heartburn, and regurgitation, the hallmark symptoms of GERD, versus placebo
    - Tegoprazan has demonstrated rapid acid control (pH>4) within 45 minutes
- Safety and tolerability for tegoprazan was favorable across all studies, with adverse events occurring at similar rates to study comparators and mean serum gastrin levels remaining within normal limits (0-180 pg/ml) throughout treatment
- Tegoprazan has already received marketing authorization in 21 countries worldwide. US approval anticipated in January 2027

**BRAINTREE, Mass., January 12, 2026** /PRNewswire/ – Braintree Laboratories, Inc. a part of Sebela Pharmaceuticals® and a leading manufacturer of gastroenterology pharmaceutical products, announced that it submitted a New Drug Application (NDA) on January 9, 2026 to the U.S. Food and Drug Administration (FDA) for tegoprazan, a novel potassium-competitive acid blocker (P-CAB), for the treatment of adults with gastroesophageal reflux disease (GERD). The NDA seeks simultaneous approval for three indications: treatment of heartburn associated with non-erosive reflux disease (NERD), healing of erosive esophagitis (EE), and maintenance of EE healing.

The NDA submission is supported by robust data from the pivotal Phase 3 TRIUMpH clinical program, which enrolled over 2,000 US patients and demonstrated tegoprazan's clinical

superiority over a PPI across multiple endpoints. All endpoints were evaluated under a prespecified hierarchical multiple testing procedure. In NERD, tegoprazan demonstrated superiority over placebo for the percentage of 24-hour heartburn-free days ($p<0.0001$ and $p=0.0006$ for tegoprazan 100mg and 50mg, respectively), as well as for percentage of days without overnight heartburn and percentage of days without regurgitation. In EE, tegoprazan demonstrated statistically superior healing compared to lansoprazole at both 2 and 8 weeks across all grades of EE (LA Grades A-D: $p<0.0001$ and $p=0.0083$ for tegoprazan 100mg at weeks 2 and 8, respectively), and in patients with severe disease (LA Grades C and D: $p<0.0001$ and $p=0.0002$ for tegoprazan 100mg at weeks 2 and 8, respectively). In the 24-week maintenance phase, tegoprazan showed superior sustained healing compared to PPI therapy in all patients ($p<0.0001$ and $p=0.0145$ for tegoprazan 100mg and 50mg, respectively). Additionally, tegoprazan demonstrated superior healing and heartburn relief in patients with severe disease. Sebela plans to present full results from the TRIUMpH program at upcoming medical meetings in 2026 and submit for publication in respected peer-reviewed journals.

“Today’s NDA submission for tegoprazan marks a transformative moment in our 40-year commitment to advancing gastroenterology care,” said Alan Cooke, President and CEO of Sebela Pharmaceuticals. “GERD affects approximately 65 million Americans, and despite the availability of acid suppression therapies, 35% to 54% of patients continue to suffer from inadequate symptom control. Tegoprazan’s results from its Phase 3 TRIUMpH program demonstrate superiority to a PPI in sustained healing of EE in even the most severe cases, and clinically meaningful relief of 24-hour heartburn, overnight heartburn and regurgitation in NERD patients. We look forward to working with the FDA to obtain marketing approval as they review our full data package. We expect to bring this important new treatment option to patients and healthcare providers in January next year.”

Philip O. Katz, MD,[†] Professor of Medicine at Weill Cornell Medicine, commented, “The emergence of potassium-competitive acid blockers represents an important advance in acid suppression therapy, offering more rapid onset and sustained gastric pH control compared to proton pump inhibitors. The TRIUMpH program data are particularly noteworthy in demonstrating tegoprazan’s potential to provide control of both heartburn and regurgitation in patients with NERD as well as improved healing rates in patients with severe erosive esophagitis. These findings suggest that P-CABs like tegoprazan may help address persistent treatment gaps that have challenged clinicians for years, particularly in patients who remain symptomatic despite conventional PPI therapy.”

**GERD - A Significant Unmet Medical Need**

GERD is a chronic, highly prevalent gastrointestinal disorder affecting approximately 65 million people in the United States. The condition significantly impacts patients’ quality of life and represents a substantial healthcare burden.[1] While PPIs have been the mainstay of GERD therapy for decades, clinical evidence demonstrates that 35% to 54% of patients fail to achieve complete

relief of symptoms with current therapy, highlighting a significant unmet need in this population. Patients with more severe erosive esophagitis and those with NERD are particularly likely to experience incomplete response with standard PPI treatment.[2,3]

**About the TRIUMpH Program**

The TRIUMpH program comprises two pivotal Phase 3 studies of tegoprazan in US patients with GERD, including both EE and NERD. The Phase 3 studies were conducted entirely in the United States and are representative of the demographically diverse US population.

The Phase 3 NERD study (NCT05587322) was a large, multicenter, double-blind study (n=800) designed to demonstrate the safety and efficacy of tegoprazan 50mg and 100mg versus placebo over 4 weeks. The Phase 3 EE study (NCT05587309) was a large, multi-center, double-blind study (n=1,250, including 463 patients with LA Grade C and D esophagitis) evaluating the safety and efficacy of tegoprazan 100mg versus lansoprazole 30mg. The study consisted of an initial healing phase (evaluated at 2 and 8 weeks) followed by a 24-week maintenance phase (tegoprazan 50mg and 100mg vs lansoprazole 15mg).

Across both pivotal studies, individual treatment-emergent adverse events occurred at a rate of <3% and were generally mild and transient. The overall rate of serious treatment-emergent adverse events in each study was <2% and similar between tegoprazan and comparator groups. 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, once-daily oral medication in the P-CAB class which has been shown to provide rapid onset of action, sustained acid control for longer periods than PPIs, and superior efficacy in healing and maintaining healing of EE. P-CABs work by reversibly binding to the gastric proton pump in a potassium-competitive manner, providing fast and potent acid suppression independent of meals. In Phase 1 pharmacodynamic studies, tegoprazan demonstrated rapid acid control (pH>4) within 45 minutes.

Tegoprazan has received marketing authorization in 21 countries worldwide. If approved by the FDA, tegoprazan would be indicated in the US for the treatment of heartburn in NERD and for the healing and maintenance of healing of EE in adults.

**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. Braintree’s lead program is tegoprazan, a novel potassium competitive acid blocker (P-CAB) which has completed its Phase 3 program in

gastroesophageal reflux disease (GERD), specifically, erosive esophagitis (EE) and non-erosive reflux disease (NERD). In addition, Sebela Women's Health obtained FDA approval for Miudella® in 2025, the first non-hormonal intra-uterine device (IUD) for contraception to be approved in over 40 years. Miudella was recently featured in Time Magazine's Best Inventions of 2025. Sebela Women's Health also has another next-generation hormonal IUD for contraception in late-stage clinical development. Sebela Pharmaceuticals has offices/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.

*[†]Dr. Katz has served as a paid consultant for Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals.*

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