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Sebela Pharmaceuticals® Announces Positive Topline Results from Phase 3 TRIUMpH Program of Tegoprazan in GERD

- Tegoprazan proves to be faster acting and more effective than a proton pump inhibitor (PPI) in the healing of erosive esophagitis (EE)
    - Met all primary and secondary endpoints in healing phase of EE
    - Demonstrated superiority over lansoprazole, a PPI, in healing at weeks 2 and 8 in all grades of EE
- Tegoprazan met all primary and secondary endpoints in non-erosive reflux disease (NERD)
    - Achieved significant improvement of both 24 hour and overnight heartburn as well as regurgitation versus placebo in NERD
- Safety and tolerability were similar to placebo and lansoprazole; mean serum gastrin levels for tegoprazan and lansoprazole remained within the normal range

BRAINTREE, Mass., April 23, 2025 /PRNewswire/ – Braintree Laboratories, a part of Sebela Pharmaceuticals® and a leading manufacturer of gastroenterology pharmaceutical products, today announced positive topline results from two pivotal US Phase 3 clinical trials evaluating tegoprazan, a novel potassium-competitive acid blocker (P-CAB), in patients with gastroesophageal reflux disease (GERD).

Across both the EE and NERD pivotal studies known as TRIUMpH, tegoprazan achieved significance in all primary and secondary endpoints tested. This included statistical superiority over a PPI (lansoprazole) in achieving complete esophageal healing at weeks 2 and 8 across all grades of EE, including the significant cohort of patients with severe disease (LA Grades C & D). In the NERD trial, tegoprazan demonstrated complete symptom relief for both heartburn (overnight and heartburn free days) and regurgitation.

The maintenance phase of the EE study will complete in Q3 2025 with a New Drug Application inclusive of both the EE and NERD indications planned for filing with FDA in Q4 2025. Braintree® intends to submit results from the TRIUMpH Phase 3 studies to a high impact, peer reviewed journal along with presentation of this data at a leading gastroenterology conference in the future.

“We are delighted with tegoprazan’s Phase 3 clinical results. Across both our EE and NERD trials, tegoprazan achieved all primary and secondary endpoints tested. This includes superior EE healing for all patients over lansoprazole at weeks 2 and 8 of treatment” said Alan Cooke, President and CEO of Sebela Pharmaceuticals®. “For over 40 years we have been committed to the gastroenterology therapeutic area and to patients affected by GI diseases. Tegoprazan offers an exciting new treatment option for individuals suffering from GERD, helping to address the substantial unmet need of patients not well-controlled by conventional PPI therapy.”

Felice Schnoll-Sussman, MD, Professor of Clinical Medicine at Weill Cornell Medical College®, Director of the Jay Monahan Center for Gastrointestinal Health, commented, “The data for tegoprazan for erosive esophagitis proves that the P-CAB class can outperform PPIs and suggests that tegoprazan may offer advantages over other agents.”

“Both heartburn and regurgitation are the cardinal symptoms of GERD, but we only typically talk about heartburn resolution. Probably because previous studies on medical therapies have not been able to show or measure reduction in regurgitation like the P-CAB tegoprazan,” said Prateek Sharma, MD, Professor at the University of Kansas School of Medicine, Current President of the American Society of Gastrointestinal Endoscopy®.

In addition, a US-based Phase 1 pharmacodynamic study has demonstrated that tegoprazan can provide more rapid acid control (pH>4) within 45 minutes, with no food effect, offering patients a truly differentiated therapeutic option.

Individual treatment-emergent adverse events occurred at a rate of $\leq$ 3% in the TRIUMpH studies 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 the PPI and placebo comparator groups. Mean serum gastrin for tegoprazan and lansoprazole remained within the normal range (0-180 pg/ml) throughout the relevant treatment periods in the 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 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.

The primary and secondary efficacy endpoints in the EE healing phase were hierarchically structured, with secondary endpoint testing commencing and continuing only if the preceding endpoints were

statistically significant. All pre-specified efficacy endpoints (Table 1) were tested and achieved statistical significance.

Table 1: TRIUMpH-EE Efficacy Endpoints
Primary Endpoint:
1. % of all patients with complete healing by Week 8 (non-inferiority)
Secondary Endpoints:
2. % of 24-hour heartburn-free days (non-inferiority)
3. % of LA Grade C/D patients with complete healing by Week 8 (superiority)
4. % of LA Grade C/D patients with complete healing at Week 2 (superiority)
5. % of all patients with complete healing by Week 8 (superiority)
6. % of all patients with complete healing at Week 2 (superiority)

The Phase 3 NERD study 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 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 and the ability to control gastric pH for longer periods of time than proton pump inhibitors (PPIs). Tegoprazan has already received marketing authorization in 19 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

[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

Sebela Pharmaceuticals, is 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. In addition, Sebela Women's Health recently obtained FDA approval for Miudella®, the first non-hormonal intra-uterine 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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