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FDA Approves Sebela Pharmaceuticals' SUFLAVE™

A New Colonoscopy Preparation that Tastes Similar to a Sports Drink

SUFLAVE™ offers the same efficacy as SUPREP® Bowel Prep Kit

BRAINTREE, Mass., June 22, 2023 — Sebela Pharmaceuticals today announced that the U.S. Food and Drug Administration (FDA) granted approval of SUFLAVE™ (polyethylene glycol, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution), for colonoscopy preparation in adults. SUFLAVE, a low-volume, safe and effective colonoscopy preparation – with a taste similar to a lemon-lime sports drink – was developed and will be marketed by Braintree Laboratories, a leader in gastroenterology and part of Sebela Pharmaceuticals.

The current active screening rate in the United States for colorectal cancer (CRC) is 72%, leaving 28% unscreened, which contributes to 153,000 CRC diagnoses and more than 52,000 deaths annually.[i,ii] Colonoscopy is the most common detection method for colorectal cancer, a leading cause of cancer-related deaths that can be managed more effectively through screening and early detection.[iii] Successful colonoscopy screening is dependent upon adequate cleansing of the colon.[iv] Despite this, available methods of liquid preparation are not widely accepted by patients due to large volumes of poor-tasting solutions, resulting in low patient compliance and the need for repeat screenings.

Additionally, colonoscopy preparation products and processes are commonly cited as a significant patient barrier to colon cancer screening,[v] reinforcing an unmet need among patients for better bowel preparation options. Tolerance of bowel preparation remains the largest deterrent for patients considering screening colonoscopy with 71% of patients saying it's the worst part of colonoscopy and 55% indicating it was the greatest deterrent to a future colonoscopy.[vi] Prep volume, palatability and patient education are three key factors in reducing prep hesitancy.

"Patients frequently struggle with the taste and volume of traditional bowel preparations – and fear related to the preparation can also negatively impact patient willingness to undergo follow-up colonoscopy if it is indicated," said Douglas K. Rex, M.D., Distinguished Professor Emeritus at Indiana University School of Medicine and a full time practicing clinical gastroenterologist. "I believe the palatable lemon-lime flavor of SUFLAVE will be a welcomed option for patients – reducing preparation hesitancy and giving more people the chance to feel comfortable during preparation and getting a successful and effective procedure."

In a head-to-head pivotal study versus SUPREP® Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) Oral Solution, 94% of patients achieved successful bowel cleansing with SUFLAVE. The majority of patients reported that SUFLAVE tastes like a sports drink, and 79% of patients found the taste neutral to very pleasant compared to SUPREP (54%). Additionally, 87% of patients found SUFLAVE tolerable to very easy to consume, and 80% of patients reported that they would ask for SUFLAVE for a subsequent colonoscopy. Rates of gastrointestinal adverse events with SUFLAVE were low (<8%).[vii]

"We believe in patient choice and are committed to improving the colon preparation process for patients. We are delighted with the FDA's approval of SUFLAVE – which has efficacy equivalent to SUPREP, but with taste similar to a sports drink," said Alan Cooke, President and CEO of Sebela Pharmaceuticals. "We are proud of the hard work and dedication of the Braintree team and the phase 3 trials investigator group who continue to bring new, better choices to people undergoing colonoscopy screening."

SUFLAVE is the latest innovation in colonoscopy preparation from Braintree Laboratories. In November 2020, the FDA approved the company's tablet preparation, SUTAB®, which has had an excellent adoption record with use by over 2 million patients.

SUFLAVE will be available by prescription to patients in the U.S. in early August.

IMPORTANT SAFETY INFORMATION
SUFLAVE™ (polyethylene glycol, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution) is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. **DOSAGE AND ADMINISTRATION**: A low residue breakfast may be consumed on the day before colonoscopy, followed by clear liquids up to 2 hours prior to colonoscopy. Administration of two doses of SUFLAVE are required for a complete preparation for colonoscopy. Each bottle must be reconstituted with water before ingestion. Each bottle and one flavor-enhancing packet are equivalent to one dose. An additional 16 ounces of water must be consumed after each dose. Stop consumption of all fluids at least 2 hours before the colonoscopy. **CONTRAINDICATIONS**: Use is contraindicated in the following conditions: Gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, hypersensitivity to any ingredient in SUFLAVE. **WARNINGS AND PRECAUTIONS**: Risk of fluid and electrolyte abnormalities: Encourage adequate hydration, assess concurrent medications and consider laboratory assessments prior to and after each use; Cardiac arrhythmias: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk; Seizures: Use caution in patients with a history of seizures and patients at increased risk of seizures, including medications that lower the seizure threshold; Colonic mucosal ulcerations: Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease; Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider laboratory testing; Suspected GI obstruction or perforation: Rule out the diagnosis before administration; Patients at risk for aspiration: Observe during administration; Hypersensitivity reactions, including anaphylaxis: Inform patients to seek immediate medical care if symptoms occur. **ADVERSE REACTIONS**: Most common adverse reactions (≥ 2%) are: nausea, abdominal distension, vomiting, abdominal pain, and headache. **DRUG INTERACTIONS**: Drugs that increase risk of fluid and electrolyte imbalance. *See Full Prescribing Information and Medication Guide*

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, a part of Sebela Pharmaceuticals, is the market leader in colonoscopy screening for over 35 years, having invented, developed and commercialized a broad portfolio of innovative prescription colonoscopy preparations and multiple gastroenterology products. Braintree also has multiple gastroenterology programs in late-stage clinical development including Tegoprazan which is in phase 3 trials for gastro-esophageal reflux disease (GERD), specifically, erosive esophagitis (EE) and non-erosive reflux disease (NERD). In addition, Sebela Women's Health has two next generation intra-uterine devices (IUDs) for contraception in the final stages of clinical development. Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland; has annual net sales of approximately $200 million; and has grown to over 320 employees through strategic acquisitions and organic growth.

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 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 SUFLAVE™; growth and opportunity, including peak sales and the potential demand for SUFLAVE™, 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 Sebela Pharmaceuticals does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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[iii] Doubeni CA, Corley DA, Quinn VP, et al. Effectiveness of screening colonoscopy in reducing the risk of death from right and left colon cancer: a large community-based study. *Gut.* 2018;67(2):291-298

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[vii] Data on File, Braintree, MA: Braintree Laboratories, Inc.