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Sebela Pharmaceuticals Receives FDA Approval for SUTAB[®] Tablets for Colonoscopy Preparation

SUTAB[®] Tablets with Active Sulfate Ingredients Give Gastroenterologists a New, Safe, and Effective Alternative to Liquid Bowel Preparations

BRAINTREE, Mass, Nov. 10, 2020— Sebela Pharmaceuticals[®] today announces that the U.S. Food and Drug Administration (FDA) approved SUTAB[®] (sodium sulfate, magnesium sulfate, and potassium chloride) tablets. SUTAB, a sulfate-based tablet preparation for colonoscopy, was developed and will be marketed by Braintree Laboratories, the makers of SUPREP[®] Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution—the market leader in branded colonoscopy preparations.¹ SUTAB gives patients and physicians an alternative to liquid-based colonoscopy preparations. Braintree, a leader in gastroenterology, is part of Sebela Pharmaceuticals.

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.² It is considered the gold standard of colorectal cancer screening methods for its ability to view the entire colon and both detect and remove polyps during the same procedure.^{3,4} Nineteen million colonoscopies are performed in the U.S. every year.⁵ For those patients, particularly those who have had difficulty completing colonoscopy preparation in the past, SUTAB presents a welcome alternative to liquid bowel preparation.

“Successful bowel prep is critical for gastroenterologists to clearly see any polyps or abnormalities, yet the immense volume of liquid prep solutions can prevent patients from adequately completing their regimens. Tablets provide a welcome alternative for successful prep completion and visualization of the colon,” said Douglas K. Rex, M.D., Director of Endoscopy at Indiana University Hospital and Professor, Department of Medicine, Division of Gastroenterology and Hepatology, University of Indiana School of Medicine.

Alan Cooke, President and CEO of Sebela Pharmaceuticals, said “Gastroenterologists and their patients have repeatedly asked for a safe and efficacious tablet bowel prep. Now patients can benefit from SUTAB, thanks to Braintree’s innovative and dedicated team, who have worked tirelessly to develop this important product. SUTAB’s FDA approval underscores Braintree’s more than thirty-five year commitment to gastroenterology.”

In two pivotal trials, 92% of patients achieved successful bowel cleansing with SUTAB⁶ and 92%-95% of patients achieved successful cleansing in all segments of the colon, including the proximal colon.⁷ In one pivotal trial, 91% of patients rated SUTAB as very easy to tolerable to consume.⁷ Seventy-eight percent said they would request SUTAB again for a future colonoscopy.⁷ Fifty-two percent of all SUTAB and MoviPrep^{®8} patients reported at least one selected gastrointestinal adverse reaction.⁶ More SUTAB patients reported experiencing nausea and vomiting than comparator, with ≤1% of these reports considered severe.⁶

“The approval of SUTAB provides a welcome relief for patients who struggle with the unpleasant taste issues commonly associated with other products for colonoscopy preparation,” said Jack A. Di Palma, M.D., Professor of Medicine and Fellowship Program Director of the Division of Gastroenterology at the

University of South Alabama College of Medicine and Past-President of the American College of Gastroenterology. “And because SUTAB contains the active sulfate ingredients similar to SUPREP, gastroenterologists will already be familiar with its effects.”

SUTAB will be available by prescription to patients in the U.S. on January 1, 2021.

IMPORTANT SAFETY INFORMATION

SUTAB[®] (sodium sulfate, magnesium sulfate, potassium chloride) tablets for oral use 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. After breakfast, only clear liquids may be consumed until after the colonoscopy. Administration of two doses of SUTAB (24 tablets) are required for a complete preparation for colonoscopy. Twelve (12) tablets are equivalent to one dose. Water must be consumed with each dose of SUTAB and additional water must be consumed after each dose. Complete all SUTAB tablets and required water at least 2 hours before colonoscopy. **CONTRAINDICATIONS:** Use is contraindicated in the following conditions: gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention. **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; 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. **ADVERSE REACTIONS:** Most common gastrointestinal adverse reactions are: nausea, abdominal distension, vomiting and upper abdominal pain. **DRUG INTERACTIONS:** Drugs that increase risk of fluid and electrolyte imbalance.⁶
See Full Prescribing Information and Medication Guide

About SUTAB[®]

SUTAB[®] (sodium sulfate, magnesium sulfate, potassium chloride) tablets for oral use is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. Cleaning the colon helps a healthcare provider see the inside of a colon more clearly during a colonoscopy.

Safety and effectiveness of SUTAB[®] in pediatric patients have not been established.⁶

About Sebela Pharmaceuticals[®]

Sebela Pharmaceuticals is a US-focused, growth-oriented specialty pharmaceutical company developing and commercializing gastroenterology, women’s health, and dermatology prescription products. Braintree, a part of Sebela Pharmaceuticals, is a pioneer in gastroenterology therapy for bowel cleansing prior to colonoscopy having developed multiple innovative prescription bowel prep and constipation products including SUTAB[®], SUPREP[®] Bowel Prep Kit, GoLYTELY[®] and NuLYTELY[®]. Our gastroenterology product line also includes Motofen[®], Analpram HC[®] and recently approved Pizensy[™] (indicated for chronic idiopathic constipation in adults). Sebela Pharmaceuticals has multiple further advances in bowel prep therapy in clinical development. Sebela Pharmaceuticals also has two next generation intra-uterine devices (IUDs) for contraception in development that hold the promise of a better patient experience in addition to excellent efficacy. Sebela Pharmaceuticals has offices in Roswell, GA; Braintree, MA; and Dublin, Ireland, has annual net sales of \$200-250 million and has grown to over 300 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 SUTAB[®]; growth and opportunity, including peak sales and the potential demand for SUTAB[®], 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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8. MoviPrep[®] (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution) is a registered trademark of Velinor AG.