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Sebela Pharmaceuticals Announces U.S. Launch of SUTAB® Tablets, An Alternative to Liquid Colonoscopy Preparation

SUTAB® Tablets with Active Sulfate Ingredients Is the First Tablet Colonoscopy Preparation to Receive FDA Approval in Over 10 Years

ROSWELL, GA, Jan 5, 2021—Sebela Pharmaceuticals® today announced that SUTAB® (sodium sulfate, magnesium sulfate, and potassium chloride) tablets, the first tablet colonoscopy preparation to receive approval from the U.S. Food and Drug Administration (FDA) in over 10 years, is now available in the United States.

SUTAB is a sulfate-based tablet colonoscopy preparation that is taken orally in a split-dose administration starting the evening before a colonoscopy. The tablets offer a safe and effective alternative to liquid colonoscopy preparations, which traditionally require consuming large volumes of poor-tasting solution and can often be a barrier to patients' willingness to undergo colonoscopy screening for colorectal cancer. [1]

The American Cancer Society and the U.S. Preventive Services Task Force recommend adults undergo screening for colorectal cancer beginning at age 45.[2] Colonoscopy is the gold standard detection method for colorectal cancer, a leading cause of cancer-related deaths that can be more effectively treated if caught early through screening.[3] Within the last decade, the rate of colonoscopy procedures has increased significantly with approximately 18 million people now screened annually for colorectal cancer.

"Alternative colonoscopy preparations, like SUTAB, can play an important role in encouraging more patients to get screened for colorectal cancer," said Alan Cooke, President and CEO of Sebela Pharmaceuticals. "With the introduction of SUTAB tablets, we hope to take yet another important step toward removing some of the burden often associated with the preparation process – allowing more patients to feel confident in their choice to undergo a colonoscopy."

The FDA approved SUTAB on November 10, 2020. The approval was based on positive Phase 3 clinical trials, which evaluated the safety and efficacy of SUTAB compared to FDA-approved preparations in 941 patients**,** including a traditional polyethylene glycol and ascorbate preparation (PEG-EA) for bowel cleansing prior to a colonoscopy.[4]

A high rate of cleaning success was seen with SUTAB (92.4%), which demonstrated non-inferiority to PEG-EA (89.3%).[4] Likewise, the percentage of patients rating their overall experience with SUTAB as "excellent" or "good" was higher than those rating PEG-EA (71.6% vs. 59.8%, respectively).[4] For a future colonoscopy, 78% of patients said they would request SUTAB again.[4]

SUTAB is now available by prescription in the U.S. and is competitively priced with other branded colonoscopy preparations. Patients can pay as little as $40 with a Braintree copay card. To learn more, visit www.SUTAB.com.

SUTAB was developed by Braintree, the makers of SUPREP® Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution for adults—the market leader in branded colonoscopy

preparations.[5] Braintree, a leader in gastroenterology, is part of Sebela Pharmaceuticals.

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 screening for colorectal cancer having developed multiple innovative prescription colonoscopy preparation 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 colonoscopy preparation 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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References:

1. Parra-Blanco A, Ruiz A, Alvarez-Lobos M, et al. Achieving the best bowel preparation for colonoscopy. *World J Gastroenterol.* Published online December 21, 2014. doi: 10.3748/wjg.v20.i47.17709
2. U.S. Preventative Services Task Force. *Colorectal Cancer: Screening*. https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/colorectal-cancer-screening3. October 27, 2020. Accessed December 21, 2020.
3. 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.
4. Di Palma JA, Bhandari R, Cleveland M, et al. A safety and efficacy comparison of a new sulfate-based tablet bowel preparation versus a PEG and ascorbate comparator in adult subjects undergoing colonoscopy. *Am J Gastroenterol.* Published online November 6, 2020. doi: 10.14309/ajg.0000000000001020
5. IQVIA. National Prescription Audit Report. December 2020.
6. SUTAB® [package insert]. Braintree Laboratories, Inc., Braintree, MA: 2020.