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, MA — Sebela Pharmaceuticals® 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 SUTAB[6] 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 ADMINSTRATION: 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 postcolonoscopy 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.

For more information, please visit: sebelapharma.com or call 800-874-6756

References

1. IQVIA. National Prescription Audit Report. September 2020.
2. 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.
3. Niederreiter M, Niederreiter L, Schmiderer A, Tilg H, Djanani A. Colorectal cancer screening and prevention—pros and cons. Memo. 2019;12;239-243.
4. Stauffer CM, Pfeifer C. Colonoscopy. In: StatPearls. Treasure Island (FL): StatPearls Publishing; July 31, 2020. Accessed October 6, 2020.
5. iData Research. An Astounding 19 Million Colonoscopies Are Performed Annually in The United States. https://idataresearch.com/an-astounding-19-million-colonoscopies-are-performed-annually-in-the-unitedstates/. August 8, 2018. Accessed October 22, 2020.
6. SUTAB® [package insert]. Braintree Laboratories, Inc., Braintree, MA: 2020.
7. 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
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.

IBD PLEXUS®

Academic Request for Proposals

The Crohn's & Colitis Foundation has released a request for proposals (RFP) for academic researchers to gain access to IBD patients' biosamples and/or research-ready datasets housed within IBD Plexus®.

IBD Plexus was founded by the Foundation to advance science, accelerate progress toward precision medicine, and improve the care of patients living with IBD. This first-of-its kind, national-scale, cloud-based platform integrates clinical, patient-reported, genetic, and other molecular data from diverse research study cohorts, real-world clinical care settings, and patients' experiences. IBD Plexus provides academic and industry researchers with access to research-ready datasets and biosamples to more rapidly perform activities that promise to speed treatment development, optimize existing therapies through development of biomarkers and diagnostics, and improve health outcomes.

IBD Plexus unites clinicians, scientists, educators, industry partners, and patients to answer questions that are critically important to advance the field of IBD research. The Foundation seeks research proposals that would utilize IBD Plexus biosamples and/or data to facilitate efforts in four

(continued on page 54)

(continued from page 52)
main areas: identification and/or validation of diagnostics/biomarkers, therapeutic development and optimization, disease management, and disease prevention.

This is a rolling solicitation. The Foundation will continue to accept responses to the RFP until all awards are distributed.

For more information visit:
crohnscolitisfoundation.org/PlexusRFP

RESEARCH UPDATE
iCURECELIAC PATIENT REGISTRY LEADS TO NEW RESEARCH FINDINGS

With your generous support, we invest heavily in celiac disease research to accelerate diagnosis, the development of treatments, and a cure. One of our most important research investments over the last several years has been in iCureCeliac®, the nation's leading celiac disease patient registry. Again and again, iCureCeliac® has helped researchers from around the world develop a greater understanding of celiac disease, leading to investment in promising interventions and therapeutics.

In October, researchers published three important studies about celiac disease that used the iCureCeliac® patient registry database as the data source. I am pleased to be able to share these studies with you.

The first study was published in the Journal of American Medical Association (JAMA) and is titled Prevalence of Dermatitis Herpetiformis Within the iCureCeliac Patient-Powered Research Network-Patient Characteristics and Dietary Counseling. Results of the University of Pennsylvania study showed patients with dermatitis herpetiformis (DH) were less likely to recall receiving counseling on a gluten-free diet at the time of diagnosis when compared with patients with celiac disease but without DH. This is likely because only 20% of patients diagnosed with DH present with classic GI symptoms associated with celiac disease at the time of diagnosis. As well, most DH diagnoses are made by dermatologists who may lack appreciation of the need to offer counseling on the gluten-free diet. As a result, DH patients who fail to adopt a strict gluten-free diet within the first 5 years of diagnosis may have an increased risk of mortality from lymphoma in this period of time.

The second study, Disease burden and quality of life impacts in patients with celiac disease on a gluten-free diet: an analysis of the iCureCeliac registry, was presented as a poster at the United European Gastroenterology Week Virtual 2020 Congress, October 11-13, 2020 and at the American College of Gastroenterology 2020 Virtual Annual Scientific Meeting, October 23-28. Authored by researchers from Takeda Pharmaceuticals and the Celiac Disease Foundation, the study presents compelling evidence that, 'despite gluten-free diet adherence, many patients with celiac disease still have symptoms that substantially impact their lives. This was seen for all patients but was most pronounced for those with higher symptom burden, highlighting the heterogeneity of celiac disease burden and need for further therapies beyond a gluten-free diet.' Takeda currently has two celiac disease drugs in development, TAK-101, which is designed to promote immune intolerance, and TAK-062, which works by enzymatically digesting gluten. Findings from iCureCeliac® continue to substantiate the need for treatment alternatives to a gluten-free diet.

Probiotics Use in Celiac Disease: Results from a National Survey, the third study, is also currently being presented at ACG 2020 Virtual and is an Outstanding Poster Presenter recipient. Led by Andrew Joelson, MD, Gastroenterology Fellow at the Celiac Disease Center at Columbia University, the study examined probiotic use in the Foundation's iCureCeliac® patient registry population finding that about one-third of patients reported using probiotics to treat persistent symptoms. Patients on a gluten-free diet who were still experiencing symptoms were twice as likely to use probiotics as patients who reported controlled symptoms. This is the Celiac Disease Foundation's fifth collaboration with Dr. Joelson and his team at Columbia University since 2017 with iCureCeliac® data demonstrating the serious burden of celiac disease.

As always, we thank you for your generous support that makes our work possible.

To Our Health
Marilyn G. Geller, Chief Executive

For the latest information on celiac disease and COVID-19, view our Resource Center.

Celiac Disease Foundation
20350 Ventura Boulevard | Suite 240
Woodland Hills, California 91364
818.716.1513
info@celiac.org