Sebela Pharmaceuticals Announces FDA Approval of Pizensy™ for oral solution for the Treatment of Chronic Idiopathic Constipation in Adults

Sebela Seeks Partner to Commercialize in the U.S.

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BRAINTREE, MA, USA --Sebela Pharmaceuticals announced today that the U.S. Food and Drug Administration (FDA) has approved Pizensy™ (lactitol) for oral solution for the once-daily treatment of chronic idiopathic constipation (CIC) in adults. Pizensy is a simple monosaccharide sugar alcohol which exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect.

"The approval of Pizensy represents a major step forward in treatment options for CIC. Pizensy will be the only FDA approved product which the patient can self-titrate based on their own results for stool consistency," 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. "Pizensy will allow practitioners and patients to jointly take control of their condition using a product with the same proven and safe mechanism of action as we have seen in bowel prep products such as SUPREP® Bowel Prep Kit."

Unlike current prescription treatments which are solid oral doses, Pizensy is mixed with the patient's fluid of choice, e.g., water, juice, coffee, tea or soda, and taken once a day at whatever time the patient prefers, preferably with food. Pizensy allows for patients to adjust the dose of the product. In the clinical trials versus placebo, approximately 25% of patients were able to at least temporarily reduce their dose.

Pizensy is expected to be available in the U.S. in the second half of 2020. Pizensy is a New Chemical Entity and is expected to have patent protection until 2037. Sebela intends to commercialize Pizensy in the U.S. with a marketing partner and has received preliminary expressions of interest from a number of interested parties.

CIC is a complex, functional GI disorder defined by symptoms including fewer than three bowel movements a week and hard-to-pass or incomplete bowel movements, for which there is no identifiable cause.[1,2] CIC affects approximately 33 million Americans and an estimated 14 percent of the global population.[2] Almost 4.7M brand prescriptions were written for products indicated for CIC in 2019, representing gross sales of $2.36B and growth rates of +6% and +16% versus 2018 respectively.[3]

The efficacy and safety of Pizensy were evaluated in three Phase 3 clinical trials which included more than 1,400 patients. These included a 6-month, double-blind, placebo-controlled study, a 12-week, blinded head to head study versus lubiprostone (AMITIZA®) and a 12-month, open-label, chronic use study.

Over the first 12-week course of treatment, patients treated with Pizensy achieved a significantly greater efficacy response compared to placebo (26% vs. 13%, $p<0.001$). This response was sustained in the Pizensy group during Weeks 13 to 24. In both pivotal trials, efficacy responders were defined as patients who had at least three complete spontaneous bowel movements (CSBMs) in a given week and an increase of at least one CSBM over baseline in the same week for at least nine out of 12 weeks, including at least three of the last four weeks.

Over course of treatment, patients who received Pizensy had statistically significant improvements as compared to placebo in stool frequency (as measured by the number of spontaneous and complete spontaneous bowel movements per week) and stool consistency (as measured by the Bristol Stool Form Scale).

The most common adverse event reported in the clinical trials versus placebo was Upper Respiratory Tract Infection at a rate of 9% compared to 6% of patients treated with placebo. Other adverse events reported at a lower frequency include flatulence and diarrhea. The rates of diarrhea and severe diarrhea were similar between the Pizensy and placebo groups. Overall discontinuation rates were low among patients treated with Pizensy at 4% as compared to placebo at 3%.

Indications and Usage
Pizensy is indicated for chronic idiopathic constipation in adults.

IMPORTANT SAFETY INFORMATION

Pizensy™ is contraindicated in patients known or suspected mechanical gastrointestinal obstruction or galactosemia.

The most common adverse reactions observed when taking Pizensy (>3%) are upper respiratory tract infection, flatulence, diarrhea, Increased blood creatinine phosphokinase, abdominal distension and high blood pressure.

The following adverse reactions have been identified during post-approval use of lactitol outside the United States, hypersensitivity reactions, including rash and pruritus.

Pizensy may reduce the absorption of concomitantly administered oral medications. Administer oral medications at least 2 hours before or 2 hours after Pizensy.

Please click here for Full Prescribing Information

About Chronic Idiopathic Constipation (CIC)
CIC affects approximately 14 percent of the global population, disproportionately affecting women and older adults.[2] People with CIC have persistent symptoms of difficult and infrequent bowel movements.[1] In addition to physical symptoms including abdominal bloating and discomfort, CIC can adversely affect an individual's quality of life, including increasing stress levels and anxiety.[1]

About Pizensy™
Pizensy™ (lactitol) for oral solution is a once-daily product wherein 20 grams of the product are mixed with 4 to 8 ounces of fluid, e.g., water, juice or soda for the treatment of chronic idiopathic constipation in adults. If the patient experiences loose stools the dose of Pizensy™ can be lowered to 10 grams mixed with 4 to 8 ounces of fluid.

About Sebela Pharmaceuticals
Sebela is a private, US focused growth-oriented specialty pharmaceutical company developing and commercializing gastroenterology, women's health and dermatology prescription products. The company is a pioneer in gastroenterology therapy for bowel cleansing prior to colonoscopy having developed multiple innovative prescription bowel prep and constipation products such as GoLYTELY®, NuLYTELY®, MiraLAX® and SUPREP® Bowel Prep Kit. Sebela has numerous further advances in bowel prep therapy in late stage clinical development including one NDA currently under review by the FDA. Sebela also has two next generation Intra-Uterine Devices (IUDs) for contraception in development which hold the promise of a better patient experience in addition to excellent efficacy.

Sebela has offices in Roswell, GA; Braintree, MA; and Dublin Ireland, has annual net sales of approximately $250 million and has grown to over 300 employees through strategic acquisitions and organic growth. Sebela's products in Gastroenterology and Dermatology maintain number one market share positions in the marketplace as branded prescription products for their indications.[3]

Please visit sebelapharma.com for more information.

Forward-Looking Statement
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 Pizensy; growth and opportunity, including

peak sales and the potential demand for Pizensy, as well as its potential impact on applicable markets; market size; substantial competition; our ability to continue as a going 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 does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

[1]Thomas R, Luthin D. Current and emerging treatments for irritable bowel syndrome with constipation and chronic idiopathic constipation: focus on prosecretory agents. Pharmacotherapy Pub. 2015; 613-630.
[2] Suares NC, Ford AC. Prevalence of, and risk factors for chronic idiopathic constipation in the community: systematic review and meta-analysis. Am J Gastroenterol. 2011; 106(9): 1582-1591.
[3]IQVIA. National Prescription Audit Report. December 2019.

SOURCE: Sebela Pharmaceuticals

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