

May 1, 2017



Synergy Pharmaceuticals to Highlight New Data for TRULANCE™ (Plecanatide) at Digestive Disease Week (DDW)

Presentations include data from a late breaker abstract with new irritable bowel syndrome with constipation (IBS-C) results and insights from the BURDEN-CIC study

NEW YORK--(BUSINESS WIRE)-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) today announced that the company will present six abstracts, including a late-breaker oral presentation showing new data on TRULANCE for the treatment of adults with irritable bowel syndrome with constipation (IBS-C), at Digestive Disease Week (DDW), May 6-9, 2017, in Chicago.

TRULANCE is a once-daily tablet approved by the Food and Drug Administration (FDA) for the treatment of adults with chronic idiopathic constipation (CIC) and is currently being evaluated for the treatment of adults with IBS-C. The recommended dosage of TRULANCE for CIC is 3 mg taken orally, once daily, with or without food at any time of the day.

Synergy will also present findings from the new BURDEN-CIC (Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients with Chronic Idiopathic Constipation) study, which evaluated the experiences and perceptions of people living with CIC and healthcare providers who regularly treat this condition. In addition, the company will present four posters, which include two that have been recognized as Posters of Distinction.

The data will be presented via oral and poster presentations as follows:

Oral Presentation

Tuesday, May 9 – 10:45 a.m.-11:00 a.m. CT

- **874k: Efficacy and Safety of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation: Results from 2 Randomized, Double-Blind, Placebo-Controlled Clinical Trials**
 - Presenter: Ronald Fogel, M.D., Clinical Research Institute of Michigan

Poster Presentations

Sunday, May 7 – 12:00 p.m.-2:00 p.m. CT

- **1533: Results from the BURDEN-CIC study (Better Understanding and**

Recognition of the Disconnects, Experiences, and Needs of Patients with Chronic Idiopathic Constipation)

- Presenter: Lucinda A. Harris, M.D., Mayo Clinic
- **1518: Plecanatide for the Treatment of Chronic Idiopathic Constipation: An Analysis of Patient-Reported Symptoms Associated with Constipation**
 - Presenter: Philip B. Miner, Jr. M.D., President and Medical Director, Oklahoma Foundation for Digestive Research
- **517: Efficacy and Safety of Plecanatide in Patients with Chronic Idiopathic Constipation: An Analysis of Patients with Moderate to Very Severe Bloating (Poster of Distinction)**
 - Presenter: Satish S.C. Rao, M.D., PhD, Professor of Medicine, Division Chief Fellowship Program Director and Director, Digestive Health Center at Augusta University
- **1531: The Uroguanylin Analog Plecanatide Activates Guanylate Cyclase C Predominantly in the Lumen of the Proximal Small Intestine to Stimulate Chloride and Fluid Secretion and Increase GI Transit in Animal Models**
 - Presenter: Apoorva Joshi, M.D., Baruch S. Blumberg Institute
- **515: Plecanatide and Dolcanatide, Guanylate Cyclase-C Agonists, Attenuate Paracellular Permeability and Enhance Normal Localization of Tight Junctional Proteins to Maintain Intestinal Barrier Function (Poster of Distinction)**
 - Presenter: Anusha Thadi, M.D., Synergy Pharmaceuticals Inc.

Indications and Usage

TRULANCE is a guanylate cyclase-C (GC-C) agonist indicated in adults for the treatment of chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Risk of Serious Dehydration in Pediatric Patients

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence $\geq 2\%$ and greater than in the placebo group) was diarrhea (5% vs 1% placebo).

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. People with CIC have persistent symptoms of difficult-to-pass and infrequent bowel movements. 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.

About Irritable Bowel Syndrome with Constipation (IBS-C)

Irritable bowel syndrome (IBS) is a chronic gastrointestinal disorder characterized by recurrent abdominal pain and associated with two or more of the following: related to defecation, associated with a change in the frequency of stool, or associated with a change in the form (appearance) of the stool. IBS can be subtyped by the predominant stool form: constipation (IBS-C), diarrhea (IBS-D) or mixed (IBS-M). Those within the IBS-C subtype experience hard or lumpy stools more than 25 percent of the time they defecate, and loose or watery stools less than 25 percent of the time. It is estimated that the prevalence of IBS-C in the U.S. adult population is approximately 4 to 5 percent,

although this number can vary as patients may fluctuate between the three subtypes of IBS.

About TRULANCE™

TRULANCE™ (plecanatide) is a once-daily tablet approved for adults with CIC and is being evaluated for IBS-C. With the exception of a single amino acid substitution for greater binding affinity, TRULANCE is structurally identical to uroguanylin, a naturally occurring and endogenous human GI peptide. Uroguanylin activates GC-C receptors in a pH-sensitive manner primarily in the small intestine, stimulating fluid secretion and maintaining stool consistency necessary for regular bowel function.

About Synergy Pharmaceuticals

Synergy is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. The company has pioneered discovery, research and development efforts on analogs of uroguanylin, a naturally occurring and endogenous human GI peptide, for the treatment of GI diseases and disorders. Synergy's proprietary GI platform includes one commercial product TRULANCE™ (plecanatide) and a second lead product candidate, dolcanatide. For more information, please visit www.synergypharma.com.

Forward-Looking Statement

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Synergy Pharmaceuticals Inc. 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 TRULANCE; growth and opportunity, including peak sales and the potential demand for TRULANCE, 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. Investors should read the risk factors set forth in Synergy's most recent periodic reports filed with the Securities and Exchange Commission, including Synergy's

Form 10-K for the year ended December 31, 2016. 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 Synergy 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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