Synergy Pharmaceuticals to Present TRULANCE™ (Plecanatide) Phase 3 Data at Digestive Disease Week (DDW) for the Treatment of Adults with Chronic Idiopathic Constipation (CIC) with Moderate to Very Severe Bloating

New data highlight results for CIC patients with moderate to very severe bloating.

NEW YORK--(BUSINESS WIRE)-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) announced today that the company will present new data from an analysis of patients with moderate to very severe bloating at baseline who participated in two Phase 3 studies evaluating TRULANCE™ (plecanatide) for the treatment of adults with chronic idiopathic constipation (CIC). These data were recognized by the American Gastroenterology Association (AGA) as a Poster of Distinction and will be presented 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 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.

Over 12 weeks, patients with CIC and moderate, severe or very severe bloating symptoms at baseline and were treated with TRULANCE 3 mg or 6 mg doses achieved a significantly greater efficacy responder rate—the primary endpoint defined by the FDA for regulatory approval in CIC—in this analysis compared to placebo (18.8% for 3 mg and 16.3% for 6 mg compared to 9.5% for placebo). 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 weeks out of the 12-week treatment period, including at least three of the last four weeks. The symptom of bloating among these patients also showed statistically significant improvements for TRULANCE 3 mg and 6 mg compared to placebo. Improvements in abdominal bloating scores were statistically significant after one week and continued throughout the 12-week treatment period.

“People living with chronic idiopathic constipation often experience a range of symptoms that can make it more difficult to manage this disorder, including moderate to very severe bloating,” said Satish S.C. Rao, M.D., Ph.D., Professor of Medicine, Division Chief
Fellowship Program Director and Director, Digestive Health Center at Augusta University. “The data presented today is consistent with the efficacy and safety results seen from previously published results for TRULANCE in CIC.”

In both studies, the most common adverse event was diarrhea (4.1% at 3 mg and 4.5% at 6 mg compared to 0.7% for placebo). Discontinuation rates were low across both groups (3.6% at 3 mg and 4.5% at 6 mg compared to 2.4% for placebo) and discontinuations due to diarrhea were infrequent (1.0% at 3 mg and 1.6% at 6 mg compared to 0.2% for placebo).

**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 ≥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 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 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 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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