Synergy Pharmaceuticals Presents New Plecanatide Phase 3 Data in Chronic Idiopathic Constipation at Digestive Disease Week

NEW YORK-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) today announced additional results from the second of two pivotal phase 3 clinical trials evaluating the efficacy and safety of plecanatide, the company’s first uroguanylin analog, for the treatment of chronic idiopathic constipation (CIC). Data were presented at Digestive Disease Week (DDW) in San Diego.

“These data show that plecanatide has the potential to address the serious unmet need for people with CIC,” said Lead Investigator Philip B. Miner, Jr., MD, President and Medical Director of the Oklahoma Foundation for Digestive Research. “Across the two largest trials conducted in CIC, plecanatide showed statistically significant improvement in chronic constipation and abdominal symptoms, such as straining and bloating, with a low rate of side effects.”

Efficacy and Safety of Plecanatide in the Treatment of Chronic Idiopathic Constipation (CIC): Results from a Multicenter Phase III Study (Study-03)

- Daily treatment with plecanatide 3 or 6 mg significantly improved durable overall complete spontaneous bowel movement (CSBM) responder rates relative to placebo [primary endpoint defined by the U.S. Food and Drug Administration (FDA) for regulatory approval in CIC].
- Improvements from baseline in CSBM and spontaneous bowel movement (SBM) frequency were noted as early as week 1 and lasted through the end of treatment.
- Significantly more patients in plecanatide groups had CSBMs and SBMs within 24 hours of the first dose of study medication.
- Straining scores improved significantly from baseline over the 12-week treatment period for each dose of plecanatide relative to placebo.
- No worsening of bowel and abdominal symptoms (including CSBM and SBM frequency) relative to baseline were observed following treatment.
- Most adverse events (AEs) were mild or moderate in severity. The most common AE was diarrhea (3.2% in 3 mg and 4.5% in 6 mg dose groups compared to 1.3% in the placebo group). Rates of discontinuation due to diarrhea were 1.1% in 3 mg and 1.1% in 6 mg dose groups compared to 0.4% in the placebo group.
Rates of discontinuation due to treatment-emergent AEs were 3.2% in 3mg and 3.8% in 6mg dose groups compared to 3.0% in the placebo group.

Serious AEs were experienced by 1.2% of patients.

Plecanatide data from the first pivotal phase 3 CIC trial and additional secondary endpoints from both trials were presented yesterday at DDW. Consistent with the results presented today, plecanatide met the primary endpoint in the first trial and significantly improved durable overall CSBM responder rates relative to placebo. Additionally, patients taking plecanatide in both trials showed statistically significant improvements in secondary endpoints for stool consistency, straining, constipation severity and treatment satisfaction scores compared to placebo.

About Chronic Idiopathic Constipation (CIC)

CIC affects 14 percent of the population in North America, disproportionately impacting women and older adults. People with CIC have persistent symptoms of difficult and infrequent bowel movements. CIC can severely impact people’s daily lives, increasing stress levels and anxiety.

About Plecanatide

Plecanatide is currently being evaluated for use as a once-daily tablet for two functional gastrointestinal (GI) disorders, CIC and irritable bowel syndrome with constipation (IBS-C). Plecanatide is a peptide made up of 16 amino acids. It is structurally similar to uroguanylin with the exception of a single amino acid change. Plecanatide is the first investigational drug designed to replicate the function of uroguanylin, a naturally occurring human GI peptide, by working locally in the upper GI tract to stimulate digestive fluid movement and support regular bowel function. In 2015, Synergy announced positive phase 3 data with plecanatide in two pivotal CIC clinical trials and on January 29, 2016, the company submitted its first new drug application (NDA) for plecanatide in CIC. If approved, Synergy plans to launch plecanatide with the CIC indication in the first quarter of 2017. Synergy presently has two ongoing phase 3 clinical trials with plecanatide in IBS-C and intends to file a second NDA in IBS-C by the end of this year.

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 around uroguanylin analogs for the treatment of functional GI disorders and inflammatory bowel disease. Synergy’s proprietary GI platform is based on uroguanylin and includes two lead product candidates – plecanatide and dolcanatide. For more information, please visit www.synergypharma.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast,"
"estimated," "expected," and "intend," among others. These forward-looking statements are based on Synergy's current expectations and actual results could differ materially. 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, 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; limited sales and marketing efforts and dependence upon third parties; 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 Form 10-K for the year ended December 31, 2015 and other periodic reports filed with the Securities and Exchange Commission. 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.

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