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Synergy Announces Positive Results From Plecanatide Phase IIb/III Trial in Patients With Chronic Idiopathic Constipation

*Topline Data Show That Plecanatide Met Primary and Key Secondary Endpoints*

NEW YORK, Jan. 2, 2013 (GLOBE NEWSWIRE) -- Synergy Pharmaceuticals, Inc. (Nasdaq:SGYP) today announced that plecanatide, its investigational oral drug for the treatment of chronic idiopathic constipation (CIC), was well tolerated and met the primary and key secondary endpoints of a Phase IIb/III clinical study. Full study results will be presented at a major scientific meeting this year.

The randomized, double-blind, placebo-controlled, repeat-dose, dose-ranging study was designed to determine whether plecanatide could increase the number of complete spontaneous bowel movements (CSBM's) and impact other parameters such as stool consistency, straining and time to first bowel movement in patients with CIC. The 12-week study, which included 951 CIC patients at 113 clinical sites in the United States, evaluated 3 doses of plecanatide (0.3, 1.0, 3.0 mg) plus a placebo arm.

Evidence of increasing efficacy was seen at increasing dose levels. Notably, the 3 mg dose in the current trial demonstrated a 19% (p=0.009) overall responder rate (vs. placebo of 10.7%), as well as demonstrating a mean increase in CSBM's over the 12-week treatment period of 2.13 (p<0.001). In addition, statistically significant improvements were seen in key secondary endpoints. The incidence of diarrhea at 3 mg was observed to be 9.7% (vs. placebo incidence of 1.3%).

"We look forward to presenting the full results of this clinical study, which confirmed the efficacy and safety of plecanatide," said Dr. Gary S. Jacob, President and CEO of Synergy Pharmaceuticals. "This trial also represents a major milestone for Synergy. We pioneered the study of analogs of the human hormone uroguanylin to treat gastrointestinal disorders in an effort to identify an agent that would normalize bowel movements with minimal diarrhea."

"Based on the results of this trial, we are convinced that plecanatide has the potential to be a safe, effective and much-needed new treatment for millions of patients who are living with chronic constipation," Dr. Jacob added.

The study, which concluded late, last month, was part of an ongoing CIC development program for plecanatide. Synergy is also conducting a Phase IIb study to assess plecanatide in the treatment of irritable bowel syndrome with constipation (IBS-C). In
addition, a Phase I study was recently completed with Synergy's second GC-C agonist, known as SP-333, for the treatment of inflammatory bowel diseases.

About Chronic Constipation

Chronic constipation is the most common digestive complaint in the United States and the world. About 15%, or 45 million people, suffer from chronic constipation in the U.S., with a similar prevalence in other developed countries. Although chronic constipation affects both men and women of every age, it disproportionately impacts women as well as the elderly, a large and growing population.

Current treatments provide temporary relief, but because they fail to address the underlying causes of chronic constipation, they do not normalize patients' bowel function. Such treatments are also associated with unpleasant side effects, the most common of which is diarrhea, causing patients to see-saw between extremes. As a result, most doctors and their patients are dissatisfied with current treatments for chronic constipation.

Chronic constipation is also a significant driver of healthcare costs. Healthcare systems are spending millions of dollars annually to diagnose and treat this disorder, including $820 million annually on over-the-counter laxatives in the U.S. alone.

About Plecanatide

Plecanatide is a member of a new class of essentially non-systemic drugs, referred to as guanylate cyclase C (GC-C) agonists, which are currently in development to treat CIC and IBS-C. Plecanatide is a synthetic analog of uroguanylin, a natriuretic hormone that regulates ion and fluid transport in the GI tract. Orally-administered plecanatide binds to and activates GC-C receptors expressed on epithelial cells lining the GI mucosa, resulting in activation of the cystic fibrosis transmembrane conductance regulator (CFTR), and leading to augmented flow of chloride and water into the lumen of the gut. Activation of the GC-C receptor pathway is believed to facilitate bowel movement as well as producing other beneficial physiological responses including improvement in abdominal pain and inflammation. In animal models, oral administration of plecanatide promotes intestinal secretion and also ameliorates GI inflammation.

About Synergy Pharmaceuticals Inc.

Synergy is a biopharmaceutical company focused on the development of new drugs to treat gastrointestinal disorders and diseases. Synergy's lead proprietary drug candidate plecanatide is a synthetic analog of the human gastrointestinal hormone uroguanylin, and functions by activating the guanylate cyclase C receptor on epithelial cells of the GI tract. Synergy completed a Phase I study of plecanatide in healthy volunteers, a Phase IIa clinical trial in CIC patients, and has just completed a major Phase IIb/III clinical trial of plecanatide to treat CIC. Plecanatide is also being developed to treat IBS-C, with the first trial in IBS-C patients initiated in the fourth quarter of 2012. Synergy's second GC-C agonist SP-333 is in clinical development to treat inflammatory bowel diseases, and has just completed its first Phase I trial in healthy volunteers. More information is available at http://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, 2011 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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