July 17, 2014

Synergy Pharmaceuticals Completes Patient Enrollment for its SP-333 Phase 2 Trial in Patients with Opioid-Induced Constipation

Top-line data for the SP-333 phase 2 OIC trial expected in the fourth quarter of 2014

NEW YORK-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) today announced that it has successfully completed patient enrollment for its phase 2 trial of SP-333, Synergy's next-generation uroguanylin analog, in patients with opioid-induced constipation (OIC).

The multi-center, randomized, double-blind clinical trial is designed to compare a 4-week dose-ranging regimen of once-daily oral SP-333 (1.0 mg, 3.0 mg and 6.0 mg) against placebo in patients taking opioid analgesics for chronic, non-cancer pain for at least three months. The study will evaluate approximately 260 patients with OIC who have less than 3 spontaneous bowel movements (SBMs) per week and who experience constipation related symptoms. The primary endpoint of the study is mean change from baseline in the number of SBMs during Week 4 of the Treatment Period.

Synergy plans to release top-line data from this trial in the fourth quarter of this year. For more information, please visit http://clinicaltrials.gov/ct2/show/NCT01983306?term=sp-333&rank=1

About SP-333

SP-333 is Synergy's next-generation uroguanylin analog in development for the treatment of OIC and mild-to-moderate ulcerative colitis. SP-333 is designed to be a highly potent and stable version of the naturally occurring gastrointestinal (GI) hormone, uroguanylin, and resistant to proteolysis in gastric intestinal fluids. SP-333 has completed phase 1 single and multiple ascending dose studies in healthy volunteers and is currently in a phase 2 clinical trial for OIC. Synergy is also developing a unique formulation of SP-333 for treating GI inflammation in patients with ulcerative colitis.

About Synergy Pharmaceuticals

Synergy Pharmaceuticals (NASDAQ:SGYP) is a biopharmaceutical company focused on the development of novel therapies based on the naturally occurring human hormone,

uroguanylin, to treat GI diseases and disorders. Synergy has created two unique analogs of uroguanylin – plecanatide and SP-333 – designed to mimic the natural hormone's activity on the intestinal guanylate cyclase-C (GC-C) receptor and target a variety of GI conditions. Plecanatide is currently in two pivotal phase 3 trials for chronic idiopathic constipation (CIC) and recently reached the halfway mark for patient enrollment in the first CIC registration trial. Synergy plans to release topline data from the first CIC registration trial in the second quarter of 2015. In April 2014, the Company announced positive top-line data results with plecanatide in a phase 2b study for irritable bowel syndrome with constipation (IBS-C). Synergy plans to initiate its pivotal phase 3 IBS-C program with plecanatide in the fourth quarter of this year. 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, 2013 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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