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# Synergy Pharmaceuticals Announces Successful End-of-Phase 2 Meeting with FDA for Plecanatide in Irritable Bowel Syndrome with Constipation

*Pivotal Phase 3 IBS-C Program to be Initiated in the Fourth Quarter of 2014*

NEW YORK-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP) today announced that it has successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) on its lead drug plecanatide for the treatment of irritable bowel syndrome with constipation (IBS-C). Agreement was reached with the FDA for the plecanatide pivotal phase 3 IBS-C clinical development program that is scheduled to begin in the fourth quarter of this year.

"We are very pleased with the outcome of our meeting with the FDA and have a clear path forward to start the IBS-C registration program with plecanatide this year," said Dr. Gary S. Jacob, Chairman and CEO of Synergy. "The pivotal phase 3 IBS-C trials will include both 3.0 mg and 6.0 mg plecanatide, which are consistent with the doses currently being evaluated in our phase 3 chronic idiopathic constipation (CIC) program. Plecanatide has demonstrated a clinical dose-response for efficacy with an excellent tolerability profile that is observed across trials. This is an important advantage as we look to bring two doses to market in both indications and provide physicians with options for addressing individual patient needs."

Synergy's pivotal phase 3 IBS-C clinical development program will consist of two registration trials, each including 1,050 patients who will receive either placebo, 3.0 mg or 6.0 mg plecanatide. IBS-C patients successfully completing either of the 12-week placebo-controlled registration trials will be offered enrollment into a long-term safety trial in order to complement and support the ongoing long-term safety database for the CIC indication.

## **About Plecanatide**

Plecanatide is Synergy's lead uroguanylin analog in late-stage clinical development to treat patients with CIC and IBS-C. Uroguanylin is a natural gastrointestinal (GI) hormone produced by humans in the small intestine and plays a key role in regulating the normal functioning of the digestive tract through its activity on the guanylate cyclase-C (GC-C) receptor. The GC-C receptor is known to be a primary source for stimulating a variety of beneficial physiological responses. Orally administered plecanatide mimics uroguanylin's functions by binding to and activating the GC-C receptor to stimulate fluid and ion transit required for normal bowel function. Synergy has successfully completed a phase 2b trial of

plecanatide in 951 patients with CIC and is currently enrolling patients in two pivotal phase 3 CIC trials. The company also recently announced positive top-line data results from a phase 2b dose-ranging study with plecanatide in patients with IBS-C.

### **About Synergy Pharmaceuticals**

Synergy Pharmaceuticals (NASDAQ:SGYP) is a biopharmaceutical company focused on the development of novel therapies based on the natural 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 GC-C receptor and target a variety of GI conditions. SP-333 is currently in phase 2 development for opioid-induced constipation and is also being explored for ulcerative colitis. For more information, please visit [www.synergypharma.com](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, 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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