Synergy Pharmaceuticals Presents Poster on Novel Mechanism of Action of SP-333, an Agonist of Guanylate Cyclase-C for Treatment of Ulcerative Colitis

Scientific Poster Presentation at 2012 Advances in IBD Conference

NEW YORK, Dec. 14, 2012 (GLOBE NEWSWIRE) -- Synergy Pharmaceuticals Inc. (Nasdaq:SGYP), a developer of new drugs to treat gastrointestinal disorders and diseases, today announced that a poster presentation on SP-333, Synergy's next-generation guanylate cyclase-C (GC-C) agonist to treat ulcerative colitis, will be made at the 2012 Advances in Inflammatory Bowel Diseases, Crohn's & Colitis Foundation's Clinical & Research Conference. The conference takes place December 13-15 at the Westin Diplomat in Hollywood, FL.

The poster describes animal studies showing that oral treatment with SP-333, an analog of uroguanylin, ameliorated gastrointestinal (GI) inflammation in dextran sodium sulfate (DSS) induced colitis in mice, and that down-regulation of NF-kB and pro-inflammatory cytokines was associated with SP-333 administration. The data also demonstrate that systemic absorption of orally administered SP-333 is minimal, and is unaffected by the severity of the experimental colitis. Synergy recently completed a single-dose, dose-escalating Phase I trial of SP-333 in healthy adult volunteers, and is planning to initiate a multi-dose, dose-escalation study in healthy volunteers in early 2013.

Recent studies suggest that expression of uroguanylin, the native GC-C agonist expressed in the human GI tract, is down-regulated in inflamed tissue from patients with Crohn's disease and in patients with ulcerative colitis, implying that uroguanylin deficiency may be associated with disruption of intestinal barrier function, one of the primary hypothesized causes of the pathogenesis of inflammatory bowel disease.

"Oral treatment with SP-333 to augment intestinal GC-C activation may represent a novel approach for restoring mucosal barrier function and suppressing inflammation," said Dr. Kunwar Shailubhai, Chief Scientific Officer of Synergy Pharmaceuticals, Inc. "In experimental models of colitis in mice, treatment with SP-333 ameliorates GI inflammation possibly through inhibition of NF-kappa B signaling to suppress production of pro-inflammatory cytokines."

The poster: **SP-333, a Guanylate Cyclase-C Agonist, Ameliorates DSS-colitis in Mice via a Novel Cyclic GMP-Mediated Mechanism (P-198)**, authored by Kunwar Shailubhai, John Foss, Graham Zhang, Krishna P Arjunan, Rong Feng, Stephen Comiskey, Gary S.
About SP-333

SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which is normally produced in the body's intestinal tract. Deficiency of uroguanylin is likely to be one of the primary reasons associated with formation of polyps as well as debilitating and difficult-to-treat GI inflammatory disorders such as ulcerative colitis and Crohn's disease. Orally-administered SP-333 binds to and activates guanylate cyclase C (GC-C) expressed on epithelial cells lining the GI mucosa, resulting in stimulation of cyclic GMP in target tissues. Its enhanced stability makes this peptide an extremely potent GC-C agonist in animal studies in mice and monkeys, promoting bowel movement in monkeys, and ameliorating GI inflammation in mice, respectively.

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 and a Phase IIa clinical trial in chronic idiopathic constipation (CIC) patients. In August of 2012, Synergy completed enrollment of patients in a major Phase II/III clinical trial of plecanatide to treat CIC. Plecanatide is also being developed to treat irritable bowel syndrome with constipation (IBS-C), with the first trial in IBS-C patients initiated in the second half of 2012. Synergy's second GC-C agonist SP-333 is in clinical development to treat inflammatory bowel diseases, and is presently in a 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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