



Synergy Pharmaceuticals

NASDAQ:SGYP

Inventing the future for GI disease

COMPANY FACT SHEET:

SYNERGY PHARMACEUTICALS

ABOUT SYNERGY PHARMACEUTICALS INC.

Synergy Pharmaceuticals [NASDAQ: SGYP] is a biopharmaceutical company dedicated to developing new drugs to treat patients with gastrointestinal disorders and diseases. Based in New York, Synergy is led by a seasoned team of scientists, clinicians and executives with extensive experience in the biopharmaceutical industry.

The company's lead investigational drug, plecanatide, is in late-stage clinical development for the treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C).

CIC and IBS-C are two of the most common gastrointestinal disorders globally, and are significant drivers of both direct and indirect healthcare costs. Currently, many doctors and their patients are deeply dissatisfied with available treatment options.

THE POTENTIAL TO ADDRESS THE UNMET MEDICAL NEEDS OF CIC AND IBS-C PATIENTS

Discovered and developed in-house by Synergy scientists and clinicians, plecanatide is a member of a new class of essentially non-systemic oral drugs known as guanylate cyclase-C (GC-C) agonists. Plecanatide, administered orally, once a day, mimics the function of the natural human peptide hormone, uroguanylin, by targeting GC-C receptors in the gut. By acting locally in the proximal intestine, plecanatide promotes intestinal fluid secretion¹ needed for normal bowel function and reduces the

SYNERGY QUICK FACTS:

HEADQUARTERS:

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FINANCIAL PROFILE:

Public company in 2008.
Listed on NASDAQ [SGYP]
in December 2012.

abdominal symptoms that are often associated with GI disorders. Plecanatide is identical to uroguanylin except for the substitution of a single amino acid, resulting in a molecule that is eight times more potent than the natural hormone.² The efficacy and safety of plecanatide for the treatment of CIC are supported by data from a large multicenter trial with 951 patients with CIC. These data are consistent with the findings in a Phase IIa study in CIC patients, and a Phase I study in healthy volunteers. Participants in the large multicenter study demonstrated an increase in complete spontaneous bowel movements (CSBMs), as well as decreased straining, stool hardness and time to first bowel movement.³

A Phase IIb clinical trial to evaluate plecanatide in the treatment of IBS-C began in December 2012, and is expected to be completed in early 2014.

EXPANDING PIPELINE

In addition to plecanatide, Synergy's clinical development pipeline includes a next-generation GC-C agonist, known as SP-333, in clinical development for the treatment of ulcerative colitis. A Phase I single ascending dose safety study of SP-333 was completed in late 2012; in January 2013, a Phase I multiple dose safety study was begun in healthy volunteers.

REFERENCES:

1. Shailubhai K. Therapeutic applications of guanylate cyclase receptor agonists. *Curr Opin Drug Discover Devel.* 2002;5(2):261-268.
2. Liu D, Overbey D, Watkinson LD, et al. In vivo imaging of human colorectal cancer using radiolabeled analogs of the uroguanylin peptide hormone. *Anticancer Res.* 2009;29:3777-3784.
3. Miner PB, Surowitz R, Fogel R, et al. Plecanatide, A Novel Guanylate Cyclase-C (GC-C) Receptor Agonist, is Efficacious and Safe in Patients with Chronic Idiopathic Constipation (CIC): Results from a 951 Patient, 12 Week, Multi-Center Trial. Oral presentation at: Digestive Disease Week® 2013; May 2013; Orlando, FL.

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