

December 19, 2017



# Synergy Pharmaceuticals Appoints Troy Hamilton Chief Executive Officer

**Co-Founder Gary S. Jacob, Ph.D., Named Executive Chairman**

NEW YORK--(BUSINESS WIRE)-- Synergy Pharmaceuticals Inc. (NASDAQ:SGYP), a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies, today announced that Troy Hamilton, Pharm.D., previously Executive Vice President, Chief Commercial Officer, has been appointed Chief Executive Officer, effective immediately. Gary S. Jacob, Ph.D., previously President, CEO and Chairman, has assumed the position of Executive Chairman of the Board of Directors.

This press release features multimedia. View the full release here:

<http://www.businesswire.com/news/home/20171219005682/en/>



Troy Hamilton, Pharm.D., Chief Executive Officer,

Mr. Hamilton joined Synergy in July 2015, and has since been responsible for building and implementing the company's commercialization infrastructure and strategy for the launch of its first product, TRULANCE<sup>®</sup>. He has over 21 years of experience in the pharmaceutical industry, with an emphasis on general management, commercialization, partnerships, acquisitions, and global product launches in the gastroenterology and primary care markets. Prior to joining Synergy, Mr. Hamilton held multiple commercial leadership roles over a nine year period within the GI Business Unit at Shire Pharmaceuticals. Before Shire, he spent most of his career at Johnson & Johnson's Janssen Pharmaceuticals and McNeil Specialty Products in a number of leadership roles.

"It has been a privilege to work alongside the Synergy team from discovery and development of our uroguanylin-based GI platform to the

Synergy Pharmaceuticals Inc. (Photo: Business Wire) commercialization of our first product earlier this year,” said Dr. Jacob. “Troy is a seasoned leader with extensive experience managing commercial operations and bringing cross functional teams together to achieve outstanding results. He understands all aspects of our corporate strategy and what we must do in order to continue to be successful moving forward. Troy was a natural choice for this role and the Board and I are confident that he is the right person to lead the company to its next phase of growth and success. With Troy as CEO, supported by his excellent and tenured commercial leadership team, Synergy is well positioned to maximize TRULANCE and capitalize on our significant market opportunities.”

“As co-founder of Synergy and co-inventor of TRULANCE, Gary has been instrumental in leading the company to where it is today – a fully integrated commercial organization – and we thank him for his continued dedication to the company,” said Mr. Hamilton. “I am excited to assume my new role and to continue working alongside the talented and dedicated management team and employees at Synergy, and grateful to our Board for this opportunity. We believe the investments we have made, along with the continued execution of our commercial strategy, have allowed us to drive early customer demand for TRULANCE in CIC and achieve expanded market access heading into 2018. We expect to build on this momentum as we move towards the PDUFA date for TRULANCE in IBS-C on January 24, 2018 and look to accelerate further growth.”

“One of my initial areas of focus will be to work with our CFO, Gary Gemignani, and the Synergy management team to continue to refine our business plan and focus on achieving cost efficiencies throughout the company while prioritizing investments that will drive significant TRULANCE growth,” added Mr. Hamilton. “As we move into 2018, we will continue to evaluate all strategic and business development opportunities to maximize the value of TRULANCE and leverage our commercial infrastructure, remaining focused on delivering long-term value for patients, healthcare providers and our shareholders.”

### **About Synergy Pharmaceuticals Inc.**

Synergy is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. The company has pioneered discovery, research and development efforts on analogs of uroguanylin, a naturally occurring and endogenous human GI peptide, for the treatment of GI diseases and disorders. Synergy’s proprietary GI platform includes one commercial product TRULANCE (plecanatide) and a second product candidate, dolcanatide. For more information, please visit [www.synergypharma.com](http://www.synergypharma.com).

### **About TRULANCE®**

TRULANCE (plecanatide) is a once-daily tablet approved for adults with CIC and is being evaluated for IBS-C. With the exception of a single amino acid substitution for greater binding affinity, TRULANCE is structurally identical to uroguanylin, a naturally occurring and endogenous human GI peptide. Uroguanylin activates GC-C receptors in a pH-sensitive manner primarily in the small intestine, stimulating fluid secretion and maintaining stool consistency necessary for regular bowel function.

## **TRULANCE Important Safety Information**

### **Indications and Usage**

TRULANCE is a guanylate cyclase-C (GC-C) agonist indicated in adults for the treatment of chronic idiopathic constipation (CIC).

### **IMPORTANT SAFETY INFORMATION**

#### **WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS**

**Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.**

### **Contraindications**

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

### **Warnings and Precautions**

#### ***Risk of Serious Dehydration in Pediatric Patients***

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

### **Diarrhea**

- Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

## Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence  $\geq 2\%$  and greater than in the placebo group) was diarrhea (5% vs 1% placebo).

Please click [here](#) for Full Prescribing Information.

## Forward-Looking Statement

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Synergy Pharmaceuticals Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. 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, the development, launch, introduction and commercial potential of TRULANCE; growth and opportunity, including peak sales and the potential demand for TRULANCE, as well as its potential impact on applicable markets; market size; 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; dependence upon third parties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; 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 most recent periodic reports filed with the Securities and Exchange Commission, including Synergy's Form 10-K for the year ended December 31, 2016. 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 except as required by law.

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## Synergy Pharmaceuticals Inc.

Gem Hopkins, 212-584-7610

VP, Investor Relations and Corporate Communications

[ghopkins@synergypharma.com](mailto:ghopkins@synergypharma.com)

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