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Synthetic Biologics Strengthens U.S. Patent Coverage of SYN-010, Intended for the Novel Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)

-- Issuance of New Patent and Allowance of Patent Application Diversifies SYN-010 Protection in US --

ROCKVILLE, Md., Sept. 26, 2019 /PRNewswire/ -- [Synthetic Biologics, Inc.](#) (NYSE American: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, announced today that the U.S. Patent and Trademark Office (USPTO) has granted a U.S. patent and issued a Notice of Allowance for a patent application covering various aspects of the clinical SYN-010 program. These USPTO issuances bolster the Company's patent portfolio supporting SYN-010, the Company's proprietary, modified-release formulation of lovastatin lactone, for the treatment of IBS-C. The current and soon-to-be issued patents will also diversify and further strengthen the IP estate covering the use of SYN-010 for the treatment of IBS-C by providing composition of matter and patient selection method of treatment claims and will provide the Company exclusivity until at least 2035.



Recently granted U.S. Patent No. 10,328,151, which is co-owned by Synthetic Biologics and Cedars-Sinai Medical Center (CSMC) and exclusively licensed to Synthetic Biologics, covers the composition of matter of the SYN-010 clinical agent. Recently allowed U.S. Patent Application No. 15/810,891, which is owned by CSMC and exclusively licensed to Synthetic

Biologics, covers methods of treating IBS-C with a statin, inclusive of SYN-010, in a selected patient population.

"Our extensive patent estate, which includes approximately 60 granted patents and 25 pending applications worldwide, continues to provide protection around our SYN-010 asset and is an important component of our ongoing focus of building long-term value for our shareholders," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "Along with the continuing Phase 2b investigator-sponsored clinical study of SYN-010 being conducted at CSMC, these successes in the USPTO provide us with further momentum in advancing SYN-010 as a much-needed treatment for the millions of patients that continue to suffer from IBS-C."

About Irritable Bowel Syndrome

IBS affects an estimated 10 to 15 percent of the U.S. population, or as many as 45 million people in North America. The illness affects both men and women; however, two-thirds of diagnosed sufferers are women. It has been reported that up to 20 percent of all IBS patients have IBS-C and current FDA-approved therapies for the treatment of IBS-C, which include prescription and over-the-counter laxatives, do little to treat the underlying cause of the disease. These products provide patients with temporary relief from the symptoms of constipation by elevating the amount of water which passes through the gastrointestinal tract, but tend to cause an IBS-C patient to swing from suffering from constipation, to suffering from diarrhea.

About SYN-010

SYN-010 is a proprietary, modified-release formulation of lovastatin lactone that is intended to reduce methane production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome to treat an underlying cause of IBS-C. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting a major cause of IBS-C, not just the symptoms. To learn more about SYN-010's unique mechanism of action, please [click here](#).

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an early-stage oral formulation of the enzyme intestinal alkaline phosphatase (IAP) designed to treat both local GI and systemic diseases. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release contains forward-looking statements within the meaning of the Private

Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and includes statements regarding the strength of the patent estate and potential benefits of SYN-004, SYN-010 and SYN-020. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability of Synthetic Biologics' product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing enrollment as expected, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004 and SYN-010 to be commenced or completed on time or to achieve desired results and benefits, a failure to file INDs when anticipated, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products, Synthetic Biologics' ability to achieve acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, Synthetic Biologics' ability to continue to comply with other continued listing requirements of the NYSE American, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel and other factors described in Synthetic Biologics' Form 10-K and 10-K/A for the year ended December 31, 2018 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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