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Synthetic Biologics Announces Allowance of Key U.S. Patent Covering SYN-010 Intended for the Novel Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)

-- Allowance of Patent Provides Exclusive Method of Use Protection Until at Least 2034 --

ROCKVILLE, Md., June 27, 2017 /PRNewswire/ --[Synthetic Biologics, Inc.](#) (NYSE MKT: 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) issued a Notice of Allowance for a patent application which covers the use of the active agent of SYN-010, the Company's proprietary, modified-release formulation of lovastatin lactone, for the treatment of constipation. Upon issuance, this patent will strengthen the intellectual property estate covering the use of SYN-010 for the treatment of IBS-C until at least 2034, affording the Company an extended term for commercialization.



U.S. Patent Application No. 14/776,465, which is owned by Cedars-Sinai Medical Center (CSMC) and exclusively licensed to Synthetic Biologics, is based on innovative research led by Mark Pimentel, M.D., FRCP(C), Program Director of CSMC's Medically Associated Science and Technology (MAST) Program and Chairman of Synthetic Biologics' IBS-C Clinical Advisory Board, which correlates methane production in the gut by certain

microorganisms (*M. smithii*) with symptoms commonly associated with IBS-C.

The allowance of this new patent expands the SYN-010 intellectual property portfolio to approximately 55 issued U.S. and foreign patents. In addition, there are approximately 25 U.S. and foreign patents pending, which upon issuance should further strengthen the intellectual property position surrounding SYN-010.

"Once issued, this patent will extend the protection around the use of SYN-010 to treat IBS-C by an additional eleven years and significantly strengthens the opportunity to build long-term value for our shareholders," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "We remain focused on the continued clinical advancement of SYN-010 and are encouraged that we are making excellent progress in providing patients with a novel, potentially best-in-class therapy that directly targets an underlying cause of the symptoms associated with IBS-C."

Previously announced results from Phase 2 clinical trials conducted by Synthetic Biologics demonstrated SYN-010 significantly reduced abdominal pain and bloating while also improving stool frequency and quality of life scores without severe adverse events in IBS-C patients. Following collaborative discussions with the U.S. Food and Drug Administration (FDA), the Company announced the approval of a Phase 2b/3 adaptive design pivotal trial intended to further evaluate the efficacy and safety of SYN-010.

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. Methane produced by *M. smithii* has been correlated with bloating, pain and constipation associated with 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 access the SYN-010 mechanism of action video on Synthetic Biologics' website, please [click here](#).

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection, pathogenic overgrowth and the emergence of antimicrobial resistance (AMR), 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 developing preclinical stage monoclonal antibody therapies for the prevention and treatment of pertussis and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU). For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release includes 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 include statements regarding the further strengthening of the patent portfolio and the continued clinical advancement of SYN-010. 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 that could cause actual results to differ materially 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, Synthetic Biologics' product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' ability to initiate clinical trials and if initiated, to complete them on time and achieve desired results and benefits, Synthetic Biologics' clinical trials continuing enrollment as expected, Synthetic Biologics' ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Synthetic Biologics' ability to promote or commercialize its product candidates for specific indications, 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 maintain its license agreements, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to establish and maintain collaborations, 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' Annual Report on Form 10-K for the year ended December 31, 2016 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, excepted as required by law.

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/synthetic-biologics-announces-allowance-of-key-us-patent-covering-syn-010-intended-for-the-novel-treatment-of-irritable-bowel-syndrome-with-constipation-ibs-c-300480127.html>

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