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

-- Company Continues to Strengthen Patent Estate Related to SYN-010 --

ROCKVILLE, Md., Feb. 17, 2016 /PRNewswire/ -- [Synthetic Biologics, Inc.](#) (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome, 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 a variety of compounds, including the active agent of SYN-010, the Company's proprietary, modified-release formulation of lovastatin lactone designed to treat a major underlying cause of irritable bowel syndrome with constipation (IBS-C).



U.S. Patent Application No. 14/211,197 also includes claims that provide protection for proprietary patient screening technology developed by Mark Pimentel, M.D., FRCP(C), Director of Cedars-Sinai Medical Center (CSMC)'s GI Motility Program and Laboratory and Chairman of Synthetic Biologics' IBS-C Clinical Advisory Board. Upon issuance, this patent, which is owned by CSMC and exclusively licensed to Synthetic Biologics, strengthens the Company's extensive SYN-010-related patent estate and extends the term of the Company's patent protection to at least 2034.

In November 2015, the USPTO issued the first U.S. patent directly pertaining to the use of SYN-010. The issuance of this new patent, which is also owned by CSMC and exclusively licensed to Synthetic Biologics, expands the SYN-010 intellectual property portfolio to approximately 55 issued U.S. and foreign patents. In addition, there are approximately 15 U.S. and foreign patents pending, which upon issuance will further strengthen the intellectual property position surrounding SYN-010.

"The allowance of this patent in conjunction with our recent announcement of positive topline data from the Phase 2 clinical trials of SYN-010, demonstrates the progress we have made toward our goal of bringing this important therapy to IBS-C patients," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "As we plan for an end of Phase 2 meeting with the FDA and to initiate Phase 3 clinical trials during 2016, we look forward to building long-term value for our shareholders."

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* is perceived as an underlying cause of 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 clinical stage company developing therapeutics to protect the microbiome while targeting pathogen-specific diseases. The Company's lead candidates in Phase 2 development include: (1) SYN-004 which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection and antibiotic-associated diarrhea (AAD), 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). In collaboration with Intrexon Corporation (NYSE: XON), the Company is developing preclinical stage monoclonal antibody therapies for the prevention and treatment of Pertussis and discovery stage biotherapeutics for the treatment of phenylketonuria (PKU). 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 include statements regarding the progress made toward the goal of bringing SYN-010 to IBS-C patients, plans for an end of Phase 2 meeting with the FDA to initiate Phase 3 clinical trials during 2016, building long term value for shareholders, SYN-004 protecting the gut microbiome from the effects of commonly used IV antibiotics for the prevention of C. difficile infection and SYN-010 reducing the impact of methane producing organisms in the gut microbiome to treat the underlying cause of IBS-C and AAD. These forward-looking

statements are based 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, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, to be commenced or completed on time or to achieve desired results, a failure of Synthetic Biologics' clinical trials to 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 and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2014 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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