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Synthetic Biologics Announces Further U.S. Patent Successes Covering SYN-004 Intended for the Prevention of *C. difficile* Infection and Antibiotic-Associated Diarrhea

-- New Allowances Bolster Strong SYN-004 Patent Estate --

ROCKVILLE, Md., March 1, 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 Notices of Allowance for three patent applications which cover composition of matter claims and methods of protecting the gut microbiome from certain beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI) and antibiotic-associated diarrhea (AAD). These new allowances further strengthen the Company's novel proprietary candidate, SYN-004, which is also covered by a composition of matter patent in the U.S.



SYN-004 is designed to degrade certain intravenous (IV) beta-lactam antibiotics excreted into the gastrointestinal (GI) tract to maintain the natural balance of the gut microbiome. *C. difficile* is associated with approximately 453,000 CDIs and > 29,000 *C. difficile*-related deaths in the United States each year[i]. Upon issuance, these newly allowed applications reinforce Synthetic Biologics' extensive *C. difficile*-related patent estate, which includes approximately 35 U.S. and foreign patents and approximately 30 U.S. and foreign patent applications, and carry patent terms that extend from at least 2031 to 2035.

"These new patents will complement our growing SYN-004 patent estate and support our *C. difficile* prevention program, including two ongoing Phase 2 clinical trials," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "We're on schedule with respect to patient enrollment in our global Phase 2b proof-of-concept clinical trial intended to evaluate the ability of SYN-004 to prevent CDI and AAD in patients hospitalized with a lower-respiratory tract infection. During the first half of 2016, we also anticipate announcing topline data from the second Phase 2a clinical trial which is evaluating the ability of SYN-004 to degrade IV ceftriaxone in the presence of a proton pump inhibitor."

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-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) and (2) 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). 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 continued patient enrollment in the global Phase 2b proof-of-concept clinical trial intended to evaluate the ability of SYN-004 to prevent CDI and AAD in patients hospitalized with a lower-respiratory tract infection, the anticipated announcement of topline data during the first half of 2016 from the second Phase 2a clinical trial which is evaluating the ability of SYN-004 to degrade IV ceftriaxone in the presence of a proton pump inhibitor and the intended benefit of SYN-010 and SYN-004. 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, 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.

[i] Leffler DA et al. N Engl J Med 2015; 372:1539-1548.

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SOURCE Synthetic Biologics, Inc.