July 7, 2016

Synthetic Biologics Receives USAN Approval for Generic Name Ribaxamase for Phase 2 Drug Candidate SYN-004

-- Ribaxamase Designed for the Prevention of C. difficile Infection, Antibiotic-Associated Diarrhea & the Emergence of Antibiotic-Resistant Organisms --

-- Oral Presentation Planned for ANAEROBE 2016 --

ROCKVILLE, Md., July 7, 2016 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases, announced today that the United States Adopted Names Council (USAN) of the American Medical Association has approved the use of "ribaxamase" (Rye-bak'-sa-mase) for Synthetic Biologics' SYN-004. Ribaxamase is the Company's Phase 2 development candidate designed to protect the gut microbiome from the unintended effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. diff*icile infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms.

Synthetic Biologics recently reported positive results from two Phase 2a clinical trials demonstrating a correlation of the 150 mg dose of ribaxamase with the degradation of residual IV ceftriaxone alone, and in the presence of the proton pump inhibitor (PPI), esomeprazole, to levels that were near or below detectable in the intestinal chyme of healthy participants with functioning ileostomies. A Phase 2b proof-of-concept, randomized, placebo-

controlled clinical trial is currently underway to evaluate the ability of ribaxamase to prevent CDI and AAD in patients hospitalized with a lower respiratory tract infection and receiving IV ceftriaxone. An interim analysis of blinded data performed by an independent data monitoring committee is expected in summer of 2016.

"The approval of the generic nameribaxamase for SYN-004 by USAN is a defining milestone for Synthetic Biologics. Ribaxamase represents a newly created and innovative first-in-class drug designed to protect the naturally occurring gut microbiome from the unintended consequences of antibiotic use," said Jeffrey Riley, President and Chief Executive Officer. "By degrading certain IV beta-lactam antibiotics before they reach the gastrointestinal (GI) tract, ribaxamase may not only prevent the onset of CDI and AAD, but has the potential to be an instrumental tool for preventing the emergence of antibiotic resistance in organisms which comprise the gut microbiome. We are excited for the continued clinical development of ribaxamase and look forward to sharing our progress including announcing results from our ongoing global Phase 2b proof-of-concept clinical trial."

Synthetic Biologics also announced that an abstract has been accepted for oral presentation at ANAEROBE 2016 taking place from July 11-14 at the Sheraton Downtown Nashville Hotel in Nashville, TN. The presentation is expected to take place during Session 10: Bacterial Replacement Therapy and is scheduled for the afternoon on Wednesday, July 13, 2016.

Presentation Title: Ribaxamase: A Pioneering Therapeutic to Protect the Microbiome from Antibiotic-Mediated Damage

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About Ribaxamase

Ribaxamase is a first-in-class oral enzyme designed to protect the gut microbiome from disruption caused by commonly used IV beta-lactam antibiotics. Ribaxamase has demonstrated in clinical trials that it is not systemically absorbed, does not interfere with the efficacy of IV beta-lactam antibiotics and, by protecting the patient's native gut microbiome, may prevent the overgrowth and associated infection with *Clostridium difficile* as well as antibiotic-associated diarrhea. Ribaxamase has the potential to protect patients from CDI and AAD which could result in shortened hospital stays, diminished morbidity and mortality and a reduction of antibiotic resistance and costs associated with the inadvertent consequences of IV beta-lactam antibiotic use.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases. The Company's lead candidates in Phase 2 development are: (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) 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 and

antibiotic-associated diarrhea (AAD). 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 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 timing of the interim analysis and the potential benefits of ribaxamase and SYN-010, including the capacity of ribaxamase to degrade residual IV ceftriaxone, in the presence of a PPI, thereby preserving the balance of the gut microbiome for the prevention of CDI, AAD and the emergence of antibiotic-resistant organisms, without affecting the antibiotic level in the bloodstream intended for the treatment of primary infection, the ability of ribaxamase to not only prevent the onset of CDI and AAD, but its potential to be an instrumental tool for preventing the emergence of antibiotic resistance in organisms which comprise the gut microbiome, the continued clinical development of ribaxamase and results from the ongoing global Phase 2b proof-of-concept clinical trial, and the potential of ribaxamase to result in shortened hospital stays, diminished morbidity and mortality and a reduction of antibiotic resistance and costs associated with the inadvertent consequences of IV beta-lactam antibiotic use. 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, 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, 2015 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-receives-usan-approval-for-generic-name-ribaxamase-for-phase-2-drug-candidate-syn-004-300295119.html

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