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# **Synthetic Biologics Awarded Research Contract from Centers for Disease Control and Prevention (CDC) for Microbiome Assessment and Intervention to Address Antibiotic Resistance**

**-- Funding to Support Ongoing Phase 2b Study to Determine SYN-004's (ribaxamase) Ability to Prevent the Emergence of Antibiotic-Resistance in the Gut Microbiome of Study Participants --**

ROCKVILLE, Md., Oct. 6, 2016 /PRNewswire/ -- [Synthetic Biologics, Inc.](http://www.syntheticbiologics.com) (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases, announced today it has been awarded a contract by the Centers for Disease Control and Prevention (CDC). The award will support research conducted during the Company's ongoing randomized, placebo-controlled Phase 2b proof-of-concept clinical study of SYN-004 (ribaxamase), designed to protect the gut microbiome from the unintended effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms.



"Antibiotics are life-saving medicines, but they also can disrupt a person's microbiome and increase the risk for drug-resistant infections," said Dr. Clifford McDonald, Associate Director of Science for CDC's Division of Healthcare Quality Promotion. "To protect people, their

microbiomes, and the effectiveness of antibiotics, this project is an example of applied research that has the potential to produce innovative public health approaches to better combat antibiotic resistance."

The contract, awarded through the CDC's Advanced and Innovative Solutions to Improve Public Health Broad Agency Announcement (BAA) 2016-N-17812, will support CDC's efforts to assess how selective pressure from IV antibiotics may lead to the emergence of antibiotic resistance in the gut microbiome. The funding will also support research to evaluate ribaxamase's ability to reduce selective pressure associated with the emergence of antibiotic-resistant organisms in the gut microbiomes of patients enrolled in the Company's ongoing Phase 2b clinical trial. The Company will examine DNA isolated from longitudinal samples obtained during the clinical trial and look for changes to the patient's gut resistome, specifically examining for alterations in the presence and/or abundance of antibiotic resistance genes.

"Synthetic Biologics is proud to have the support of the U.S. Government in its efforts to study the role of antibiotics in mediating resistance in the gut microbiome," said Jeffrey Riley, President and Chief Executive Officer. "Ribaxamase's strategy of degrading certain IV beta-lactam antibiotics before they are excreted into the GI tract has the potential to protect the gut microbiome from disruption by these antibiotics without inhibiting their ability to fight primary infections as well as mitigate conditions conducive to antibiotic-resistance development. We look forward to our collaboration with CDC and to furthering their initiative to assess and address rising global concerns for the proliferation of antibiotic resistance."

### **About the Centers for Disease Control and Prevention (CDC)**

The Centers for Disease Control and Prevention (CDC) serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish its mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

### **About SYN-004 (ribaxamase) and the Ongoing Phase 2b Study**

SYN-004 (ribaxamase) is a first-in-class oral enzyme designed to degrade certain IV beta-lactam antibiotics within the GI tract and maintain the natural balance of the gut microbiome for the prevention of CDI, AAD and the emergence of antibiotic-resistant organisms. The ongoing Phase 2b proof-of-concept clinical trial is intended to evaluate the effectiveness of ribaxamase to prevent the onset of *C. difficile* infection (CDI), *C. difficile* associated diarrhea (CDAD), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms in patients hospitalized with a lower respiratory infection and receiving intravenous (IV) ceftriaxone. The Company anticipates announcing top-results from this study during the first quarter of 2017. To access the ribaxamase 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 gut microbiome while targeting pathogen-specific diseases. The Company's lead candidates poised for Phase 3 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) 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, antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. 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](http://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 potential of Ribaxamase to protect the gut microbiome from disruption by these antibiotics without inhibiting their ability to fight primary infections as well as mitigate conditions conducive to antibiotic-resistance development, the potential of the project to produce innovative public health approaches to better combat antibiotic resistance and the intended results to be achieved by use 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 and 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 ability to successfully design a protocol and a corresponding statistical analysis plan to support the execution of the first pivotal clinical trial for SYN-010, 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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SOURCE Synthetic Biologics, Inc.