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Synthetic Biologics Announces First Patient Dosed in Phase 1a Clinical Trial of SYN-004 for the Prevention of C. difficile Infection

-- First-in-Class Clinical Program Targets Protection of Microbiome to Prevent Overgrowth of Deadly C. difficile Infection Linked with Use of IV Antibiotics --

ROCKVILLE, Md., Dec. 2, 2014 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of pathogen-specific therapies for serious infections and diseases, with a focus on protecting the microbiome, today announced that enrollment has initiated and the first patient was dosed in a Phase 1a clinical trial of SYN-004, an investigational oral beta-lactamase enzyme for the prevention of *Clostridium difficile (C. difficile)* infection (CDI), antibiotic-associated diarrhea (AAD) and secondary antibiotic-resistant infections in patients receiving intravenous (IV) beta-lactam antibiotic therapy.

The randomized, double-blind, placebo-controlled Phase 1a study, which is now underway at Clinical Pharmacology of Miami, is designed to evaluate the safety, tolerability and pharmacokinetics of five single-ascending doses of oral SYN-004 in healthy volunteers. In all, up to 40 healthy adult volunteers will be enrolled into five cohorts, with approximately six participants receiving SYN-004 and two receiving placebo in each cohort. Before the end of the year, topline Phase 1 data is expected to be reported and a Phase 1b study evaluating multiple-ascending doses of SYN-004 is planned to begin.

"The initiation of the clinical program for SYN-004 represents an important milestone for Synthetic Biologics and a key step towards the first potential point-of-care preventative therapy for *C. difficile,* the CDC's top-ranking public health threat," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "We look forward to moving Synthetic Biologics' innovative therapeutic approach to prevent *C. difficile* infection through clinical development, and further validating the connection between protecting the gut microbiome and a variety of GI, metabolic and CNS disorders."

Currently, there is no vaccine or drug approved by the U.S. Food and Drug Administration (FDA) specifically for the prevention of *C. difficile* infection, which the U.S. Centers for Disease Control (CDC) has identified as an "urgent public health threat" and occurs mostly in people who have had recent medical care with IV antibiotics. These antibiotics can create a harmful imbalance in the gut microbiome by killing "good" bacteria, giving *C. difficile* a chance to multiply and cause diarrhea, which can lead to dehydration, fever, abdominal pain, cramping, nausea, colitis, and even death. In all, 24 million Americans receive IV antibiotics annually[i].

SYN-004 is Synthetic Biologics' oral drug candidate designed to be the first and only treatment intended to prevent the development of *C. difficile* infection, by binding with and neutralizing certain common IV beta-lactam antibiotics in the gut. During 2012, 14.4 million patients in the U.S. received approximately 117.6 million doses of SYN-004 susceptible IV antibiotics[ii]. SYN-004 is intended to block the unintended harmful effects of antibiotics within the gastrointestinal (GI) tract, maintaining the natural balance of the bacterial flora (gut microbiome), potentially preventing the 1.1 million *C. difficile* infections[iii] and 30,000 *C. difficile*-related deaths[iv] in the U.S. each year.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a clinical-stage biotechnology company developing pathogen-specific therapies for serious infections and diseases, with a focus on protecting the microbiome. The Company is developing an oral biologic to protect the gastrointestinal (GI) microflora from the effects of intravenous (IV) antibiotics for the prevention of *C. difficile* infection, an oral treatment to reduce the impact of methane producing organisms on constipation-predominant irritable bowel syndrome (C-IBS) and a monoclonal antibody combination for the treatment of Pertussis being developed in collaboration with Intrexon Corporation (NYSE: XON). In addition, the Company is developing a Phase 2 oral estriol drug for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release includes forward-looking statements on Synthetic Biologics' current expectations and projections about future events. 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. These statements are based upon current beliefs, expectations and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and include statements regarding the anticipated timing of the Synthetic Biologics' clinical trials and data reports, intended benefits to be achieved from use of SYN-004, including the potential prevention of C. difficile infections, and the potential market for SYN-004. The forward-looking statements are subject to 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 those reflected in Synthetic Biologics' forward-looking statements 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'

products for the prevention and treatment of diseases to be successfully developed or commercialized, Synthetic Biologics' inability to maintain its 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, 2013 and any other filings with the SEC. 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] This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

[ii] This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

[iii] This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: CDM Hospital database for full year 2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

[iv] U.S. Department of Health & Human Services. Agency for Healthcare Research and Quality. January 25, 2012. http://www.ahrq.gov/news/nn/nn012512.htm Accessed: September 30, 2013.

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