December 22, 2014

Synthetic Biologics Announces Positive Topline Results from Phase 1a Trial of SYN-004 for the Prevention of C. difficile Infection

-- First-in-Class Drug Candidate to Prevent C. difficile Ahead of Schedule for Phase 2 Testing to Begin in 1st Quarter 2015 --

ROCKVILLE, Md., Dec. 22, 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 positive topline safety and tolerability results from a Phase 1a clinical trial of SYN-004, the Company's investigational oral beta-lactamase enzyme for the prevention of *Clostridium difficile (C. difficile)* infection, antibiotic-associated diarrhea and secondary antibiotic-resistant infections in patients receiving intravenous (IV) beta-lactam antibiotic therapy.

Since December 2nd, the randomized double-blind, placebo-controlled Phase 1a clinical trial conducted at Clinical Pharmacology of Miami, has enrolled 24 healthy volunteers in three cohorts of eight patients each. A total of 18 volunteers have been administered one dose of SYN-004 at increasing dose levels by cohort, and six volunteers received placebo. No clinically significant or relevant adverse events have been reported to date.

"Completing the first safety review and reporting positive topline results in the Phase 1a clinical trial of SYN-004 is an important event for Synthetic Biologics, bringing us closer to the first potential point-of-care preventative therapy for *C. difficile,* the CDC's top-ranking public health threat. Achieving this milestone moves us closer to validating our ground-breaking approach to preventing *C. difficile* infection in a way that protects the gut microbiome, which also holds the hope of treating a variety of GI, metabolic and CNS disorders," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics.

Mr. Riley added, "Based on the results observed in the first three cohorts, and per our clinical plan, we intend to proceed with our planned multiple-ascending dose placebo-

controlled Phase 1b study of SYN-004, in which healthy volunteers will receive increasing doses of SYN-004 over several days. We expect enrollment into our Phase 1b SYN-004 clinical trial to begin before year-end, with topline data available during the first quarter of 2015. We also expect to initiate enrollment in a Phase 2 SYN-004 clinical trial ahead of schedule during the first quarter of 2015."

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

The U.S. Centers for Disease Control (CDC) has identified *C. difficile* 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[iv].

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 statin 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 enrollment in 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] 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.

[iv] 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.

Photo - https://photos.prnewswire.com/prnh/20130522/MM19465LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-announces-positive-topline-results-from-phase-1a-trial-of-syn-004-for-the-prevention-of-c-difficile-infection-300012855.html

SOURCE Synthetic Biologics, Inc.