November 24, 2014

Synthetic Biologics Safe-to-Proceed Under IND to Initiate Clinical Trials of SYN-004 for the Prevention C. difficile Infection

-- Phase 1a and 1b Trials to Use SYN-004 to Protect Microbiome; Intended to Prevent Overgrowth of Potentially Deadly C. difficile Bacteria --

ROCKVILLE, Md., Nov. 24, 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 its Investigational New Drug (IND) application which was submitted to the U.S. Food and Drug Administration (FDA) in October will be proceeding into clinical trials for the development of the Company's oral beta-lactamase enzyme SYN-004 for the prevention of *Clostridium difficile (C. difficile)* infection (CDI), antibiotic-associated diarrhea (AAD) and secondary infections with healthcare-acquired, drug-resistant pathogens in patients receiving intravenous (IV) beta-lactam antibiotic therapy. Synthetic Biologics plans to begin Phase 1a and 1b clinical trials shortly, with topline data expected to be reported before year-end.

"We are pleased the FDA completed the 30-day review of our IND and to be initiating clinical trials of 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. "Taking immediate and aggressive action to develop a therapy that can prevent *C. difficile* before it starts is critical in addressing this pervasive and life-threatening infection, and IND activation for SYN-004 is a key step toward the development and eventual commercialization of therapy to protect the millions of at risk U.S. patients."

C. difficile is a widespread infection that 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], and the Company believes there is currently no vaccine or drug approved for the prevention of *C.*

difficile infection.

SYN-004 is Synthetic Biologics' oral drug candidate designed to be the first and only prophylactic treatment intended to prevent the development of *C. difficile* infection, by binding with and neutralizing certain common IV beta-lactam antibiotics in the gut. 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[ii] and 30,000 *C. difficile*-related deaths[iii] in the U.S. each year.

Mr. Riley added, "In addition to antibiotics being a key trigger in the development of *C. difficile* infection, research continues to point to the fact that disruption of the gut microbiome due to antibiotic usage, as well as the steady rise in antibiotic-resistant superbugs, are causative factors for a variety of GI, CNS and metabolic disorders, including obesity and diabetes. SYN-004 may be the solution."

Synthetic Biologics has met each milestone for its *C. difficile* program leading up to the IND submission to the agency. Clinical drug manufacturing of SYN-004 under cGMP guidelines to support Synthetic Biologics' planned Phase 1 and 2 clinical trials was completed on time to support the IND submission and clinical trial initiation. Most recently, the U.S. Patent and Trademark Office issued a Notice of Allowance for the first composition of matter patent application directly pertaining to SYN-004 in the U.S., which carries a patent term to at least 2031.

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] 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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