May 16, 2016

Synthetic Biologics Announces Positive Topline Results from Second Phase 2a Clinical Trial of SYN-004 for the Prevention of C. difficile Infection and Antibiotic-Associated Diarrhea

-- SYN-004 Degraded IV Ceftriaxone in the Presence of a Proton Pump Inhibitor in the Gastrointestinal Tract without Affecting Antibiotic Levels in the Bloodstream --

-- Two Poster Presentations Planned for ASM Microbe 2016, Including Detailed Data from Two SYN-004 Phase 2a Open-Label Clinical Trials --

ROCKVILLE, Md., May16, 2016 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a clinical stage company focused on developing therapeutics to protect the gut microbiome, announced positive topline results from the second Phase 2a open-label clinical trial of SYN-004, the Company's 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. difficile* infection (CDI), antibiotic-associated diarrhea (AAD) and the emergence of antibiotic-resistant organisms. Results from 14 participants who completed this clinical trial were analyzed to assess the ability of the 150 mg dose of SYN-004 to degrade ceftriaxone when administered alone and with the proton pump inhibitor (PPI), esomeprazole.

Consistent with previously reported results from the first Phase 2a clinical trial, the second Phase 2a trial demonstrated that the 150 mg dose of SYN-004 degraded residual IV ceftriaxone alone, and in the presence of a PPI, to levels that were near or below detectable in the intestinal chyme of healthy participants with functioning ileostomies. In addition, ceftriaxone plasma concentrations in study participants were very similar in the presence or absence of an oral PPI. The 150 mg dose strength of SYN-004 was well tolerated by all participants in this clinical trial.

"These topline data support the hypothesis that SYN-004 has the capacity to degrade residual IV ceftriaxone, in the presence of a PPI, thereby preserving the balance of the gut microbiome with the intent to prevent CDI, AAD and the emergence of antibiotic-resistant organisms, without affecting the antibiotic level in the bloodstream necessary for the treatment of primary infection," said Jeffrey Riley, President and Chief Executive Officer of Synthetic Biologics. "Our Phase 2b proof-of-concept, randomized, placebo-controlled clinical trial has enrolled over 210 patients to evaluate the ability of SYN-004 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."

Synthetic Biologics also announced that two abstracts have been accepted for poster presentation at ASM Microbe 2016. Both posters will be available for viewing in Halls A and B at the Boston Convention & Exhibition Center on Friday, June 17, from 12:30 to 2:30 p.m. (EDT), as part of the "Experimental Therapeutics" session.

Poster: 456
Title: SYN-004, an Oral β-Lactamase to Prevent *Clostridium difficile*, Degrades Ceftriaxone Excreted in the Human Intestine in Phase 2a Trials
Authors: J. F. Kokai-Kun[1], T. Roberts[1], E. Sicard[2], M. Rufiange[2], R. Fedorak[3], C. Carter[3], O. Coughlin[1], H. Whalen[1], K. Gottlieb[1], J. Sliman[1]; [1]Synthetic Biologics, Inc., Rockville, MD, [2]Algorithme Pharma, Laval, QC, Canada, [3]Univ. of Alberta/Alberta Hlth. Service, Edmonton, AB, Canada

Poster: 446
Title: Development of Orally-Delivered Therapeutics to Protect the Gut Microbiome from Antibiotic-Mediated Damage
Authors: S. Connelly[1], C. Freguia[1], T. Parsley[2], N. Hasan[3], P. Subramanian[3], M. Kaleko[1]; [1]Synthetic Biologics, Inc., Rockville, MD, [2]SynPhaGen, LLC., Rockville, MD, [3]CosmosID, Inc., Rockville, MD

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) SYN-004 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). In collaboration with Intrexon Corporation, 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 SYN-004 and SYN-010, including the capacity of SYN-004 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. 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, 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-announces-positive-topline-results-from-second-phase-2a-clinical-trial-of-syn-004-for-the-prevention-of-c-difficile-infection-and-antibiotic-associated-diarrhea-300268669.html

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