Synthetic Biologics Highlights New Data from C. difficile Program Presented at the 54th ICAAC

ROCKVILLE, Md., Sept. 7, 2014 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a biotechnology company developing novel anti-infective biologic and drug programs targeting specific pathogens that cause serious infections and diseases, announced today preclinical data that further validate the Company's novel approach to preventing Clostridium difficile (C. difficile). The U.S. Centers for Disease Control has identified C. difficile as an "urgent public health threat," and it has surpassed MRSA as the number one hospital-acquired infection in the United States. The data were highlighted on September 6th at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), in Washington, D.C.

Synthetic Biologics' Senior Vice President, Research & Development, Mike Kaleko, M.D., Ph.D., presented a late-breaking poster demonstrating the broad activity of its lead anti-infective candidate SYN-004 (P3A), as well as a potential pipeline candidate, P4A, for C. difficile prophylaxis. Both SYN-004 and P4A effectively degraded a broad spectrum of commonly used intravenous (IV) antibiotics that can lead to C. difficile infections, including cephalosporins.

"We were honored to have the opportunity to present our novel program for the prevention of C. difficile infection, including both SYN-004 and P4A. SYN-004 is designed to protect the gastrointestinal (GI) microflora – or gut microbiome – from the effects of certain commonly used IV antibiotics, thereby preventing C. difficile infection," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "We are in the final stages of preparing the Investigational New Drug (IND) application for SYN-004, with the expectation of initiating Phase Ia and Ib clinical trials in the fourth quarter of 2014, and a Phase II efficacy study in the first half of 2015."

About C. difficile Infections

C. difficile is classified by the CDC as an "urgent public health threat," given its high prevalence and resistance to many drugs used to treat other infections. It affects 1.1 million Americans and causes 30,000 deaths each year,[i] adding an estimated four to seven hospitalization days per patient[ii] and $8.2 billion in overall annual hospital costs.[iv] C. difficile infections are strongly associated with the use of IV antibiotics, which are administered to more than 24 million Americans annually to prevent or treat infections.[v] These powerful antibiotics can create a harmful imbalance in the gastrointestinal tract by wiping out helpful, "good" bacteria, and allowing C. difficile to grow out-of-control, leading to severe diarrhea, damaging the colon, and in some cases, death.[vi]

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a biotechnology company focused on the development of novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and diseases. The Company is developing an oral biologic to protect the gastrointestinal microflora from the effects of IV antibiotics for the prevention of Clostridium difficile (C. difficile) infection, an oral treatment to reduce the impact of methane producing organisms on constipation-predominant irritable bowel syndrome (C-IBS), a series of monoclonal antibodies for the treatment of Pertussis and Acinetobacter infections, and a biologic targeted at the prevention and treatment of a root cause of a subset of IBS. In addition, the Company is developing an 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 design of SYN - 004, Synthetic Biologics' expected initiation of Phase Ia and Ib clinical trials in the fourth quarter of 2014, and a Phase II efficacy study in the first half of 2015 and the size of the market. 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, the additional clinical studies and results not meeting expectations, the inability to commence and complete clinical trials when anticipated 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.

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