August 28, 2014

Synthetic Biologics and FUJIFILM Diosynth Biotechnologies UK Announce Significant Improvement in API Manufacturing of SYN-004 for the Prevention of C. difficile

-- Fujifilm's pAVEway™ Platform Demonstrated >25-fold Improvement in SYN-004 Expression Titers --

ROCKVILLE, Md., Aug. 28, 2014 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and diseases, and FUJIFILM Diosynth Biotechnologies UK Limited (Fujifilm), announced today confirmation of exceptional results from the initial phase of cGMP manufacturing of SYN-004, Synthetic Biologics' proprietary oral beta-lactamase enzyme for the prevention of *Clostridium difficile* (*C. difficile*) infections.

The initial 750-liter cGMP production run on Fujifilm's pAVEway™ platform yielded an unprecedented 5.5 kilograms of >95% pure SYN-004 *active pharmaceutical ingredient (*API) drug substance, which will be used to support Synthetic Biologics' planned Phase I and II clinical trials, and continued research and development studies.

SYN-004 is believed to be the first and only therapy designed to neutralize intravenous (IV) antibiotics in the gut. It is intended to protect and maintain the balance of bacterial flora in the gastrointestinal (GI) tract, or gut microbiome, and to potentially prevent the devastating effects of *C. difficile* infection. Research continues to demonstrate that protection of the microbiome plays an increasingly important role in the prevention of a variety of GI, metabolic and CNS disorders. The U.S. Centers for Disease Control and Prevention (CDC) have classified *C. diff* as an "urgent public health threat", surpassing Methicillin-resistant *Staphylococcus aureus* (MRSA) as the number one hospital-acquired infection in the United States. *C. difficile* is a multidrug-resistant bacterium that infects 1.1 million U.S. patients annually,[1] and 30,000 patients die with a *C. difficile* infection annually[2].

"We are extremely impressed by the quality, quantity and efficiency of the initial SYN-004 API manufacturing work by Fujifilm," stated Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "Fujifilm not only exceeded our yield expectations, but also provided exemplary customer service through its diligent approach and skillful execution in developing the cGMP process for SYN-004."

Mr. Riley concluded, "Importantly, with a solid new GMP manufacturing process, Synthetic Biologics remains on schedule to file an Investigational New Drug (IND) application for SYN-004, and initiate Phase Ia and Ib clinical studies for the prevention of *C. difficile* infection in the second half of 2014. Preliminary Phase I topline data is expected by year-end 2014, and a Phase II efficacy study of SYN-004 is planned to begin in the first half of 2015."

The GMP manufacturing process was initiated after a successful evaluation by Fujifilm that produced high yielding cell lines that exhibited consistent biological activity of SYN-004. Fujifilm successfully improved SYN-004 expression titers by greater than 25-fold (14 grams of SYN-004 per liter of culture broth), compared to the *Bacillus* platform previously employed for SYN-004's first-generation predecessor. Fujifilm's pAVEway™ platform (an *E. coli* system) utilizes proprietary expression vectors harboring palindromic DNA looping to provide tightly controlled gene expression, which can enable very high expression levels. The newly developed, single chromatography column purification process reproducibly yielded 40-50% SYN-004 drug substance recovery at purity levels great than 95%, another marked manufacturing improvement over the previous purification process.

Steve Bagshaw, Chief Executive Officer of FUJIFILM Diosynth Biotechnologies said, "We are pleased to demonstrate the remarkable versatility of our pAVEway™ expression system, and support Synthetic Biologics' clinical development of its SYN-004 product. We look forward to a productive relationship with Synthetic Biologics as its API supplier."

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.

About FUJIFILM Diosynth Biotechnologies

FUJIFILM Diosynth Biotechnologies UK Limited is an industry leading biologics Contract Development and Manufacturing Organization. FUJIFILM Diosynth Biotechnologies has extensive experience in the development and manufacturing of recombinant proteins, vaccines, monoclonal antibodies, among other large molecules expressed in a wide array of microbial, mammalian, and insect systems. The company offers a comprehensive list of services from microbial and mammalian cell line development, including its proprietary

pAVEway™ system, to process development, analytical development, clinical and commercial manufacturing. FUJIFILM Diosynth Biotechnologies is also located in Research Triangle Park, NC, USA as FUJIFILM Diosynth Biotechnologies U.S.A., Inc. Both sites have been FDA-approved for the production of commercial biologic products.

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 intended effects and potential impact of SYN-004, the timing of initiation of the Phase Ia and Ib clinical studies, the preliminary Phase I topline data and initiation of Phase II efficacy study and the expected size of the market for C. diff therapeutics. 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, our inability to timely commence or complete the clinical trials consistent with our current expectations and otherwise demonstrate the ability of SYN-004 to have a significant impact on mitigating the effects of C. difficile, our ability to successfully manufacture cGMP product, receive regulatory approvals for or to commercialize a new product candidate to prevent C. diff infection 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.

[1] 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.

[2] 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.

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

SOURCE Synthetic Biologics, Inc.