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Synthetic Biologics Highlights SYN-005 Data Presented at the 54th ICAAC from Novel Whooping Cough (Pertussis) Program

-- SYN-005 Neutralizing Antibody Combination Protects Against Pertussis in Murine and Non-Human Primate Models --

ROCKVILLE, Md., Sept. 8, 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 that data from its novel SYN-005 program for the treatment of Pertussis were highlighted in an oral presentation on September 7th by Jennifer Maynard, Ph.D., at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Washington, D.C. SYN-005 combines two highly synergistic humanized monoclonal antibodies (mAbs) designed to target and neutralize pertussis toxin.



Pertussis is a highly contagious disease caused by the bacteria *Bordetella pertussis* (*B. pertussis*) with symptoms that include severe coughing and subsequent breathing difficulties. Antibiotic use does not have a major effect on the disease course because, while it can

eliminate the *B. pertussis* bacteria from the respiratory tract, it does not neutralize pertussis toxin. This secreted toxin is a major cause of disease virulence as it paralyzes the immune system, causes the white blood cell count to increase (sometimes to levels that block blood flow through the lungs) and predisposes infants to severe pneumonia.

Pertussis can be fatal in infants; therefore, attacking pertussis toxin in infants is an urgent unmet medical need. According to the World Health Organization, *B. pertussis* causes an estimated 300,000 deaths worldwide each year, primarily among young, unvaccinated infants.

Dr. Maynard's presentation described the design and evaluation of the mAbs that comprise SYN-005. The two humanized mAbs were protective when used both individually and in combination in a murine model of respiratory Pertussis. SYN-005-treated animals continued to gain weight, demonstrated reduced bacterial colonization in the lungs, and did not experience the rise in the white blood cell count that is characteristic of the disease.

SYN-005 also was shown to be efficacious in a recently described, highly relevant non-human primate Pertussis model. Treatment of infected animals halted the rise in the white blood cell count and accelerated the resolution of coughing as well as the clearance of pertussis bacteria.

Mike Kaleko, M.D., Ph.D., Senior Vice President of Research & Development for Synthetic Biologics stated, "We are pleased to have the opportunity to showcase our Pertussis program at the ICAAC meeting. The *in vivo* studies and, in particular, the efficacy data in the non-human primates demonstrate the exceptional potential for SYN-005 to treat Pertussis and diminish the morbidity and mortality of this devastating disease in infants. Synthetic Biologics remains on track to file an Investigational New Drug (IND) application and initiate a Phase I clinical trial during the first half of 2015 and has requested Orphan Drug designation for SYN-005 in this indication."

Dr. Maynard is an Associate Professor at The University of Texas at Austin's McKetta Department of Chemical Engineering. Her oral presentation on Synthetic Biologics' SYN-005 was part of the "Neonatal Infections and the Case for Maternal Immunization" session at ICAAC.

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-005, the potential for SYN-005 to treat Pertussis and diminish the morbidity and mortality and the planned IND filing and Phase I clinical trial. 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 expected 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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