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Synthetic Biologics Reports Preclinical Data Demonstrating SYN-005 Provides Protection from Pertussis in Neonatal Animal Study

-- Study Results Further Support Advancement of SYN-005 into Clinical Trials for Treatment and Prevention of Pertussis --

-- Poster Presentations Planned for ECCMID and ESPID Conferences, Including Data from Prophylaxis Study --

ROCKVILLE, Md., April 19, 2017 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a late-stage clinical company developing therapeutics that preserve the microbiome to protect and restore the health of patients, today announced positive data for SYN-005, the Company's orphan drug program for the prevention and treatment of pertussis (whooping cough). SYN-005 combines two highly synergistic humanized monoclonal antibodies (hu1B7 and hu11E6) to target and potentially inactivate the life-threatening pertussis toxin that causes disease symptoms.

To assess the potential of SYN-005 to prevent pertussis, a non-human primate study was designed to determine if administration of hu1B7, one component of SYN-005, at two days of age could protect animals from a subsequent pertussis infection. Control animals (n=6), infected with *Bordetella pertussis (B. pertussis)* at five weeks of age, demonstrated marked elevations in white blood cell counts and most exhibited behavioral signs of pertussis,

including coughing and diminished activity. In contrast, the experimental animals (n=7), who were treated with hu1B7 at two days of age and then infected five weeks later, had significantly lower peak white blood cell counts (p=0.004) that remained within the normal range or were only slightly elevated. Importantly, all seven of the animals that received prophylactic hu1B7 appeared healthy and none exhibited any behavioral signs of pertussis.

An additional animal received hu1B7 at two days of age; however, infection with *B. pertussis* was delayed to a time point when hu1B7 was no longer detectable in the blood. As expected, in the absence of hu1B7, the animal developed a high white blood cell count and behavioral signs of pertussis. These data further support that protection from pertussis was, in fact, due to hu1B7.

Building on this early success, the Company has initiated preclinical testing of a modified version of hu1B7 that has the potential to extend the plasma half-life and substantially reduce the required dose of SYN-005.

The Company previously reported that SYN-005 was highly efficacious as a therapeutic in non-human primates infected with *B. pertussis*. The current study expands the potential clinical utility beyond therapy to also include prophylaxis.

Pertussis, more commonly known as whooping cough, is a highly contagious disease caused by the bacteria *Bordetella pertussis (B. pertussis*). The disease can prove fatal in infants and children, with symptoms of infection including chronic coughing and subsequent breathing difficulties. According to the World Health Organization, there are approximately 50 million worldwide cases of whooping cough each year, leading to an estimated 300,000 deaths, primarily among young, unvaccinated infants. Antibiotic use does not have a major effect on the course of pertussis because, while antibiotics may eliminate the *B. pertussis* bacteria from the respiratory tract, they do not neutralize the pathogenic pertussis toxin, a key virulence factor.

"There is a pressing need for new and innovative agents to address the re-emergence of pertussis as a rising global health concern, particularly in the developing world where the mortality rate for at-risk newborns is highest," said Jeffrey Riley, President and Chief Executive Officer. "Positive results from this non-human primate study suggest that SYN-005 may be able meet this need by preventing pertussis infection among high risk individuals. These data, along with those from our earlier therapeutic studies, provide strong support for advancing SYN-005 to clinical trials for both the prevention and treatment of pertussis, especially in newborns."

Synthetic Biologics is developing SYN-005 through its Exclusive Channel Collaboration with Intrexon Corporation (NYSE: XON) and academic researchers led by Dr. Jennifer Maynard, associate professor in the McKetta Department of Chemical Engineering at The University of Texas at Austin, to prevent the development of pertussis in at-risk newborns and to target and neutralize the pertussis toxin in order to reduce morbidity and mortality in infected infants. In 2015, The Bill & Melinda Gates Foundation awarded a grant to UT Austin to generate preclinical proof-of-concept data to test the hypothesis that antibody administration at birth may have a role in the prevention of pertussis. Dr. Maynard is principal investigator of The Gates Foundation grant and this prophylaxis study.

"We are greatly encouraged by these results, which clearly demonstrate hu1B7, a

humanized anti-pertussis toxin monoclonal antibody, protected neonatal primates from developing pertussis for at least five weeks," said Dr. Jennifer Maynard. "These data give us increased confidence that pertussis prophylaxis using hu1B7 may be a viable option to protect newborns for several months after birth when the risk of pertussis mortality is highest."

Synthetic Biologics also announced that two abstracts have been accepted for presentation at ECCMID 2017 and ESPID 2017. Dr. Jennifer Maynard will present a poster at ECCMID and a talk at ESPID.

European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)
April 22, 2017 from 15:30 p.m. – 16:30 p.m. CEST
Poster: 0464
Title: Monoclonal Antibody Administration Provides Five Weeks of Prophylaxis in Newborn Baboons: PoC for Passive Immunization to Protect Infants in the Developing World
Authors: **J.A. Maynard[1]**, A. Nguyen[1], R.F. Wolf[2], J.F. Papin[2], S. Connelly[3], M. Kaleko[3]; [1]University of Texas at Austin, Austin, TX,[2]University of Oklahoma Health Science Center, Oklahoma City, OK, [3]Synthetic Biologics, Inc., Rockville, MD, USA

European Society for Pediatric Infectious Diseases (ESPID)
May 25, 2017 from 14:40 p.m. – 16:10 p.m. CEST
ESPID Symposium 2: Prevention of Pertussis in Infants – The Ongoing Challenge
Title: Antibody Administration Effectively Treats Pertussis in a Baboon Disease Model and Provides Five Weeks of Pertussis Prophylaxis in Newborn Baboons
Authors: **J.A. Maynard[1]**, A. Nguyen[1], R.F. Wolf[2], J.F. Papin[2], S. Connelly[3], M. Kaleko[3]; [1]University of Texas at Austin, Austin, TX,[2]University of Oklahoma Health Science Center, Oklahoma City, OK, [3]Synthetic Biologics, Inc., Rockville, MD, USA

About SYN-005

SYN-005 combines two highly synergistic humanized monoclonal antibodies (mAbs) to target and potentially inactivate the life-threatening pertussis toxin. In preclinical therapeutic and prophylactic studies, SYN-005 was associated with significant reductions in white blood cell count and bacterial loads in non-human primate and murine animal models. Synthetic Biologics further strengthened its intellectual property position around pertussis antibodies with additional patent filings, including the granting of a U.S. Composition of Matter patent for SYN-005. In September 2014, the U.S. Food and Drug Administration (FDA) granted Orphan Drug designation for SYN-005 for the treatment of pertussis.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 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 (ribaxamase) 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 (CDI), antibiotic-associated diarrhea (AAD) and the emergence of

antimicrobial resistance (AMR). 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 positive results from the non-human primate study suggesting that SYN-005 may be able meet a pressing need by preventing the development of pertussis in high risk individuals, the confidence that pertussis prophylaxis using hu1B7 may be a viable option to protect newborns for several months after birth when the risk of pertussis mortality is highest, the size of the market, and the potential benefits of SYN-004 and SYN-010. 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' ability to successfully design a protocol and a corresponding statistical analysis plan to support the execution of its pivotal clinical trials, 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 by competitors that render Synthetic Biologics' products obsolete or non-competitive, 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, 2016 and its 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/synthetic-biologics-reports-preclinical-data-demonstrating-syn-005-provides-protection-from-pertussis-in-neonatal-animal-study-300441557.html

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