October 22, 2014

Synthetic Biologics Announces Allowance of Key U.S. Composition of Matter Patent for C. difficile Program

-- First Allowed Patent Application Directly Related to SYN-004 in the U.S. --

ROCKVILLE, Md., Oct. 22, 2014 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE MKT: SYN), a biotechnology company developing novel pathogen-specific therapies for serious infections and diseases, announced today that the U.S. Patent and Trademark Office has issued a Notice of Allowance for a composition of matter patent application that covers the lead product in its *C. difficile* program, SYN-004. This is Synthetic Biologics' first allowed patent application directly pertaining to SYN-004 in the U.S. and adds to the Company's extensive *C. difficile* patent estate.

SYN-004 is Synthetic Biologics' novel oral enzyme drug candidate designed as the first and only prophylactic treatment intended to prevent the development of *C. difficile* infections, by binding with and neutralizing certain intravenous (IV) beta-lactam antibiotics in the gut. SYN-004 is intended to block the effects of antibiotics within the gastrointestinal (GI) tract, maintaining the natural balance of bacterial flora (the gut microbiome), potentially preventing the 1.1 million *C. difficile* infections in the U.S. each year[i]. The U.S. patent to be issued has claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004, and carries a patent term to at least 2031. In addition to the newly allowed patent, the Company has numerous related granted and pending U.S. and international patent applications that are central to the Synthetic Biologics' intellectual property estate.

"This new patent will strengthen the protection of Synthetic Biologics' SYN-004 and reiterates our position as a key player in the prevention of microbiome-based diseases," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "We continue to bolster the Company's patent estate while making progress towards our goals to initiate Phase Ia and Ib *C. difficile* clinical trials this quarter."

About *C. difficile* Infections

C. difficile is classified by the U.S. Centers for Disease Control and Prevention (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,[ii,iii] adding an estimated four to seven hospitalization days per patient[iv] and $8.2 billion in overall annual hospital costs.[v] *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.[vi] These powerful antibiotics can create a harmful imbalance in the GI 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.[vii]

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE MKT: SYN) is a biotechnology company developing novel pathogen-specific therapies for 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 continued bolstering or the patent estate, the goals of initiating Phase Ia and Ib C. difficile clinical trial this quarter, the market size. 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 failure to initiate trials within the anticipated time frame, 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.

i	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.

ii	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.
iii	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.
iv	(APIC) National Prevalence Study of *Clostridium difficile* in U.S. Healthcare Facilities. November 11, 2008.http://hospitalacquiredinfections.blogspot.com/2008/12/november-11-2008-association-for.html Accessed: September 30, 2013.
v	Agency for Healthcare Research and Quality. Healthcare and Cost Utilization Project. Statistical Brief #125. Clostridium difficile Infections (CDI) in Hospital Stays, 2009. January 2012. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb124.pdf Accessed: October 1, 2013.
vi	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.
vii	Committee to Reduce Infection Deaths Web site http://www.hospitalinfection.org/preventing_cdiff.shtml Accessed: September 30, 2013.

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