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Synthetic Biologics to Acquire Clinical-Stage C. difficile Infectious Disease Program

-- Novel Oral Biologic Designed to Protect Patients from C. difficile Infection Associated with Systemic Antibiotics --

ROCKVILLE, Md., Nov. 12, 2012 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of synthetic biologics and innovative medicines for serious infections and diseases, announced today that the Company has entered into an agreement with Prev AbR LLC to acquire its clinical-stage and related beta-lactamase assets targeted for the prevention of *Clostridium difficile* (*C. diff*) infection, the leading cause of hospital acquired infections (HAI), that may occur secondary to treatment with antibiotics. The assets include a pre-Investigational New Drug (IND) package, Phase I and Phase II clinical data, manufacturing process data and all issued and pending U.S. and international patents intended to support an IND and Biologic License Application (BLA) with the FDA.

Beta-lactamase enzymes have the ability to degrade beta-lactam antibiotics that may be excreted into the GI tract. Beta-lactam antibiotics are a mainstay in hospital infection management and include both penicillins and cephalosporins. In 2011, an estimated 8.7 million Americans were administered intravenous beta-lactam antibiotics.[1] Utilizing the acquired biologic compounds, Synthetic Biologics intends to develop and commercialize a proprietary oral beta-lactamase enzyme product candidate, SYN-004. When co-administered with beta-lactam antibiotics in a hospital setting, it is expected that SYN-004 can preserve a patient's gastrointestinal (GI) microflora, thus preventing opportunistic *C. diff* infection (CDI).

C. diff Infection

In 2009, aggregate costs associated with CDI-related stays in the hospital were $8.2 billion in the U.S.[2] CDI is a global HAI in which the toxins produced by *C. diff* bacteria result in diarrhea (*C. diff*-associated diarrhea (CDAD)), and in the most serious cases, pseudomembranous colitis (erosion of the GI tract) that can lead to death. A major, unintended risk in the use of systemic antibiotics is the development of CDI, which may alter the balance of the GI microflora that normally protect the GI tract from *C. diff* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay, underlying illness, immune-compromising conditions including the administration of chemotherapy, and advanced age.

CDI is a widespread and often drug resistant infectious disease, resulting in more than 337,000 hospitalizations and 30,000 deaths in the U.S. during 2009.[3] CDI has surpassed methicillin-resistant staphylococcus aureus (MRSA) as the most frequent infection acquired in the hospital. It has recently been reported by The Centers for Disease Control and

Prevention that the current number of CDI cases may be as high as 500,000 annually in the U.S. Controlling the spread of CDI has proven challenging, as the *C. diff* spores are easily transferred to patients via the hands of healthcare personnel. There is currently no vaccine or approved product for the prevention of *C. diff* infection.

Synthetic Biologics' Product Candidate: SYN-004

The acquisition includes the clinical-stage and related beta-lactamase assets, P1A, P2A and P3A (now known as SYN-004). Phase I studies of P1A, the first compound in the series, showed acceptable safety and tolerability. In addition, two Phase II clinical studies demonstrated its ability to preserve GI microflora in hospitalized patients treated with intravenous ampicillin or the combination of piperacillin and tazobactam.

SYN-004 has a broader spectrum of activity against beta-lactam antibiotics, including both penicillins and most cephalosporins. Due to the structural similarities between P1A and SYN-004, and based on previous discussions with the FDA, it is anticipated that the preclinical and manufacturing data collected on P1A may be used in support of an IND for Synthetic Biologics' new product candidate, SYN-004, for the prevention of CDI.

"We are pleased to add the *C. diff* program to our infectious disease pipeline that also includes an acinetobacter infection program. The need for an alternative mechanism of action to prevent the devastating effects of *C. diff* infection is critical. It is important to both improve patient care and to combat the burden of rising medical costs associated with hospital-acquired infections such as *C. diff*," stated Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "Current therapies to treat *C. diff* are not universally effective and efforts to stop the spread of the disease have proven challenging. With regulatory discussions already initiated, we are designing a regulatory pathway for our new product, SYN-004, that is intended to lead to a Phase II clinical trial as soon as possible. We look forward to reporting progress from our *C. diff* program when milestones are achieved."

About Synthetic Biologics, Inc.

Synthetic Biologics is a biotechnology company focused on the development of product candidates for serious infections and diseases. Synthetic Biologics is developing a biologic for the prevention of *C. diff* infection, and a series of monoclonal antibodies (mAbs) for the treatment of serious infectious diseases, including *Acinetobacter*. The Company is also developing a synthetic DNA-based therapy for the treatment of pulmonary arterial hypertension (PAH). In addition, the Company is developing a drug candidate for the treatment of relapsing-remitting multiple sclerosis (MS) and cognitive dysfunction in MS, and designing a clinical development pathway for the treatment of amyotrophic lateral sclerosis (ALS). 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 our intention to develop and commercialize a proprietary beta-lactase

enzyme product candidate using the acquired assets that will have the desired results, our intention to commence a Phase II clinical trial and to obtain FDA approval of an IND and/or BLA for the new product candidate 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, our inability to successfully develop, receive regulatory approvals for or to commercialize a new product candidate to treat C. diff infection, the failure of clinical results for SYN-004 to support the results obtained for P1A or achieve desired results and other factors described in Synthetic Biologics' report on Form 10-K/A for the year ended December 31, 2011 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] GlobalData. Beta-lactam Antibiotics Sales -United States of America, 2011. Prepared for Synthetic Biologics, Inc. November 2012.

[2] Agency for Healthcare Research and Quality. Healthcare and Cost Utilization Project. Statistical Brief #124. *Clostridium difficile* Infections (CDI) in Hospital Stays, 2009.January 2012. Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb124.pdf.

[3] U.S. Department of Health & Human Services. Agency for Healthcare Research and Quality. January 25, 2012. Available at http://www.ahrq.gov/news/nn/nn012512.htm. Accessed November 5, 2012.

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