Synthetic Biologics Initiates Development of Monoclonal Antibodies for Treatment of Acinetobacter Infections

-- Acinetobacter Infections Pose Growing Concern in Hospitals, and in Military and Natural Disaster Trauma Centers --

-- Company Engages Former Pfizer/Wyeth Global Infectious Disease Pharmaceutical Executive to Provide Expertise on Advancing Infectious Disease Pipeline --

ANN ARBOR, Mich., Sept. 18, 2012 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of synthetic biologics and innovative medicines for serious diseases and unmet medical needs, today announced that it has initiated efforts to develop a monoclonal antibody (mAb) therapy for the treatment of acinetobacter infections. Many strains of *Acinetobacter* are multidrug-resistant and pose an increasing global threat to hospitalized patients, wounded military personnel and those affected by natural disasters. The Company also announced that it has engaged Lewis (Lew) Barrett, former Assistant Vice President, Established Products at Pfizer and Vice President Global Business Manager, Infectious Diseases at Wyeth Pharmaceuticals, to bring his expertise in the development, commercialization and launch of infectious disease product candidates to the Synthetic Biologics’ team.

*Acinetobacter* is a difficult to treat pathogen due to its rapid and well-established resistance to most antibiotics, making it a multidrug-resistant pathogen[1]. In addition, as a biofilm-forming pathogen, *Acinetobacter* has the ability to survive up to twice as long as non-biofilm-forming pathogens[2]. In the U.S., *Acinetobacter* has been reported to be the cause of up to 2.6% of hospital acquired infections, 1.3% of bloodstream infections and 7% of ICU respiratory tract infections[3], and more than half of the *Acinetobacter* isolates are multidrug-resistant[4]. Patients with infections caused by *Acinetobacter* have been reported having mortality rates ranging from 7.8% to 43% in the hospital and in the ICU[5]. While *Acinetobacter* is a well-documented pathogen in the hospital setting, this pathogen also poses an increasing danger to wounded servicemen and women in military treatment centers[6] and to those treated in trauma centers following natural disasters[7].

The initiation of mAb development for the treatment of acinetobacter infection is the first of the three initial targeted infectious diseases the Company intends to pursue as part of its most recent collaboration with Intrexon Corporation. In August 2012, Synthetic Biologics entered into a worldwide exclusive channel collaboration with Intrexon Corporation for the development and commercialization of mAb therapies to treat certain infectious diseases.
not adequately addressed by existing therapies. Under this collaboration, the Company intends to utilize Intrexon's comprehensive suite of proprietary technologies, including the mAbLogix™ and LEAP™ platforms, to develop fully human mAbs to specifically and rapidly neutralize/clear acinetobacter pathogens. The collaboration may optionally be expanded to include up to an additional five infectious disease indications.

"We are pleased to begin work on a mAb therapy to treat acinetobacter infections. *Acinetobacter* has developed an increased resistance to antibiotics and other drugs over time, and a new therapeutic option is needed to treat infectious diseases caused by this bacteria," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics, Inc. "Our collaboration with Intrexon provides access to state-of-the-art platforms that have tremendous potential to produce a broad spectrum of fully human antibodies to fight against *Acinetobacter* where other options have failed."

Mr. Riley concluded, "We welcome Lew Barrett to our team and look forward to benefiting from his many years of experience around the development and commercialization of anti-infectives, as we develop mAbs for the treatment of acinetobacter infections. We also look forward to disclosing additional infectious disease indications we intend to pursue in the near future."

During his 25-year career at Wyeth (acquired by Pfizer in 2009), Mr. Barrett successfully led, co-chaired or served as the senior marketing executive on teams that focused on infectious diseases, oncology, transplantation, and hemophilia. He brings to Synthetic Biologics his expertise in U.S. and global strategy, domestic/global branding, clinical development, medical affairs, supply chain, business development and strategic alliance management. He built the brand and led global commercialization efforts for Wyeth's in-line IV antibiotic, Zosyn®/Tazocin® (the second IV antibiotic to achieve $1 billion+ in sales), and managed the U.S. launch of Wyeth's broad-spectrum IV antibiotic, Tygacil®. In 2010, Mr. Barrett formed LL Barrett Biopharmaceutical Consulting, LLC, and utilizing his depth of experience in the anti-infective, hospital and biopharma fields, provides strategic consultation to the global life sciences field with a particular focus on brand strategy, lifecycle strategy, business development, and strategic communications.

"*Acinetobacter* has consistently demonstrated its ability to rapidly develop resistance to antibiotics. We believe the threat of this pathogen coupled with a scarcity of new antibiotics creates a perfect storm. Novel biologic therapies such as Synthetic Biologics' mAbs, with new targets and mechanisms, are especially exciting," stated Mr. Barrett. "I look forward to working with the Company as they work toward developing new therapeutic candidates for a field of medicine where the availability of effective interventions has declined."

**About Monoclonal Antibodies (mAbs)**

Acting as the body's army, antibodies are proteins, generally found in the bloodstream, that provide immunity in detecting and destroying pathogens, such as viruses and bacteria and their associated toxins. MAbs can also be designed and produced as therapeutic agents, utilizing protein engineering and recombinant production technologies. The mAbs being developed under the Synthetic Biologics' collaboration with Intrexon are intended to supplement a patient's own immune system by providing the means to specifically and
rapidly neutralize and/or clear specific pathogens and toxins of interest in a process known as "passive immunity". Many pathogens that cause infectious diseases are innately resistant to, or over time have developed increased resistance to, antibiotics and other drugs. Synthetic Biologics intends to utilize Intrexon's comprehensive suite of proprietary mAb design and recombinant protein production technologies to efficiently create potent candidate mAbs for human testing and use to specifically treat certain infectious diseases for which current therapies are unavailable or inadequate.

About Synthetic Biologics, Inc.

Synthetic Biologics is a biotechnology company focused on the development of product candidates to address serious diseases and unmet medical needs. Synthetic Biologics is developing the following synthetic biologic candidates: a series of monoclonal antibodies (mAbs) for the treatment of serious infectious diseases not adequately addressed by existing therapies and a synthetic DNA-based therapy for the treatment of pulmonary arterial hypertension (PAH). The Company is also developing drug candidates for the treatment of relapsing-remitting multiple sclerosis (MS), cognitive dysfunction in MS, amyotrophic lateral sclerosis (ALS) and fibromyalgia (partnered with Meda AB). For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

mAbLogix™ and LEAP™ are registered trademarks of Intrexon Corporation.

Zosyn®, Tazocin® and Tygacil® are registered trademarks of Pfizer or its affiliates.

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 Synthetic Biologics' intent to develop and commercialize monoclonal antibody therapies for infectious diseases, its use of Intrexon's technologies, the opportunity presented by Acinetobacter's ability to resist antibiotic therapy and the expected contributions of Lewis Barrett. 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, a failure of Synthetic Biologics' monoclonal antibodies for the treatment of infectious diseases to be successfully developed or commercialized, a failure of the Intrexon's intellectual property to create potent candidate mAbs, an inability to obtain regulatory approval of the infectious disease product candidates, a failure of the results of clinical trials to support the efficacy or safety of product candidates, a failure to successfully integrate newly engaged team members, a failure of the preclinical or clinical trials to proceed on schedules that are consistent with Synthetic Biologics' current expectations or at all, Synthetic Biologics' inability to protect its intellectual property and freedom to operate without interference of the patents of others, inability to maintain the effectiveness of the exclusive collaboration agreement, its reliance on third parties to develop its product candidates, the insufficiency
of existing capital reserves to fund continued operations for a particular amount of time and uncertainties regarding Synthetic Biologics’ ability to obtain additional financing to support its operations thereafter 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.


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