

April 4, 2013



# Synthetic Biologics Announces Issuance of U.S. Patent Covering Combination of Estriol and Copaxone® for Multiple Sclerosis

**-- Patent Expands Company's Patent Portfolio to Include Combination with Number One Selling Multiple Sclerosis Drug --**

ROCKVILLE, Md., April 4, 2013 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE MKT: SYN), a developer of synthetic biologics and innovative medicines for serious infections and diseases, announced today that the U.S. Patent & Trademark Office has issued U.S. Patent No. 8,372,826 entitled, *Estriol Therapy for Multiple Sclerosis and Other Autoimmune Diseases*, to the Regents of the University of California which includes claims to the use of the Company's drug candidate, Trimesta™ (oral estriol), in combination with glatiramer acetate injection (Copaxone®). Copaxone® is the number one selling drug for multiple sclerosis with approximately \$4 billion in annual sales. Currently marketed exclusively by Teva Pharmaceutical Industries Ltd., Copaxone® is expected to face generic competition as certain patent terms begin to expire in 2014.[1] Through its wholly owned subsidiary, Synthetic Biologics holds the exclusive worldwide license to U.S. Patent 8,372,826 and 6,936,599 and pending patents for multiple sclerosis and other autoimmune diseases covering the uses of its drug candidate, Trimesta™.

Trimesta™ is currently being utilized in combination with Copaxone® in a randomized, double-blind, placebo-controlled Phase II clinical trial for the treatment of relapsing-remitting multiple sclerosis in women. Lead Principal investigator, Rhonda Voskuhl, M.D., Director, University of California, Los Angeles (UCLA) Multiple Sclerosis Program, UCLA Department of Neurology, along with investigators at 14 other centers in the U.S., are administering either Trimesta™ (8 milligrams orally per day) in combination with Copaxone® (20 milligrams per day), or a placebo plus Copaxone® to patients enrolled in the trial.

"The claims in this new patent further expand Synthetic Biologics' coverage of our proprietary oral estriol product candidate, Trimesta™, to include its use in combination with the leading FDA-approved multiple sclerosis drug, Copaxone®," stated Jeffrey Riley, Chief Executive Officer at Synthetic Biologics. "We look forward to reporting the clinical results of this combination therapy after the relapsing-remitting multiple sclerosis patients complete their two years of dosing and monitoring scheduled for January 2014."

The 164-patient relapsing-remitting multiple sclerosis trial is fully enrolled and it is anticipated that the last patient will complete their last visit during January 2014. The primary outcome measure for the study is the rate of relapse between the placebo and treated groups at two years, an accepted FDA-approvable endpoint in MS. The clinical trial is supported by grants

exceeding \$8 million, awarded by the National Multiple Sclerosis Society in partnership with the National Multiple Sclerosis Society's (NMSS) Southern California chapter, and the National Institutes of Health.

### **About Synthetic Biologics, Inc.**

Synthetic Biologics, Inc. (NYSE MKT: SYN) 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. difficile* infection, and a series of monoclonal antibodies for the treatment of serious infectious diseases, including pertussis and *Acinetobacter*. The Company is also developing a synthetic DNA-based therapy for the treatment of pulmonary arterial hypertension. In addition, the Company is developing a drug candidate 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](http://www.syntheticbiologics.com).

To download Synthetic Biologics' investor relations mobile device app, which allows users access to the Company's SEC documents, press releases and events, please click on the following links to download the IRapp on your [iPhone and iPad](#) or your [Android mobile device](#).

Copaxone® is a registered trademark of Teva Pharmaceutical Industries Ltd.

*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 timing of completion of the 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, a failure to of patients to successfully complete the trial 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] Teva Pharmaceutical Industries Ltd. Form 20-F filed with the SEC for the year ended December 31, 2012.

SOURCE Synthetic Biologics, Inc.