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Synthetic Biologics Announces Completion of Enrollment in 164 Patient Clinical Trial of Oral Trimesta™ for Multiple Sclerosis

ANN ARBOR, Mich., March 14, 2012 /PRNewswire/ -- Synthetic Biologics, Inc. (NYSE Amex: SYN), a developer of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses, announced today that patient enrollment has been completed in a Phase II clinical trial evaluating the efficacy and safety of Synthetic Biologics' proprietary oral formulation of estriol (Trimesta™) for the treatment of relapsing-remitting multiple sclerosis (MS). With over $8 million in external grant funding awarded to date, this Trimesta clinical trial should be fully funded to its completion.

"The completion of patient enrollment into the Phase II Trimesta trial represents another important milestone for oral estriol and brings us one step closer to offering a new oral treatment option to patients with relapsing-remitting MS," said Jeffrey Riley, Chief Executive Officer of Synthetic Biologics. "As an oral therapy with a promising clinical profile, Trimesta is expected to be extremely well positioned to provide an important treatment option for this debilitating disease."

The randomized, double-blind, placebo-controlled, multi-center Phase II clinical trial of Trimesta (oral estriol) for relapsing-remitting MS in women initially enrolled a total of 164 patients. At 15 sites in the United States, clinical investigators have been administering either oral Trimesta or matching placebo in addition to glatiramer acetate (Copaxone®), an FDA-approved therapy for MS, to women between the ages of 18-50 who have been recently diagnosed with relapsing-remitting MS. MS patients are being dosed and monitored for two years. 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. Additional information regarding the relapsing-remitting MS clinical trial is available at http://www.clinicaltrials.gov/ct2/show/NCT00451204.

Current sales of injectable disease-modifying therapies for MS are estimated at $8.9 billion annually. According to various reports, sales of oral disease-modifying therapies for MS, of which Trimesta™ if and when approved would be in such class, are anticipated to exceed $5 billion annually by 2017.

"We are pleased to complete the enrollment of a total of 164 patients in this landmark MS trial," said Rhonda Voskuhl, M.D., Director, University of California, Los Angeles (UCLA) Multiple Sclerosis Program, UCLA Department of Neurology, and lead Principal Investigator of the trial. "In the United States alone, over 200 people per week are diagnosed with MS, and approximately 70% of them are women. Typically, relapsing-remitting MS is

distinguished from the other forms of MS by the relapses, or attacks of declining neurologic function, followed by periods of remission. With this trial evaluating oral estriol (Trimesta), we would expect to demonstrate a reduction in the rate of relapses in these MS patients."

About Trimesta (oral estriol)

Trimesta is Synthetic Biologics' proprietary drug candidate for the treatment of relapsing-remitting MS in women. Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the treatment of post-menopausal hot flashes. It has never been approved by the FDA for any indication in the United States.

It has been scientifically documented that pregnant women with certain autoimmune diseases experience a spontaneous reduction of disease symptoms during pregnancy, particularly in the third trimester. The PRIMS (Pregnancy In Multiple Sclerosis) study, a landmark clinical study published in the *New England Journal of Medicine* followed 254 women with MS during 269 pregnancies, and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71 percent ($p < 0.001$) through the third trimester of pregnancy compared to pre-pregnancy-rates, and that relapse rates increased by 120 percent ($p < 0.001$) during the first three months after birth (post-partum) before returning to pre-pregnancy rates.

It has been hypothesized that the female hormone, estriol, produced by the placenta during pregnancy, plays a role in "fetal immune privilege," a process that prevents a mother's immune system from attacking and rejecting her fetus. Maternal levels of estriol increase in a linear fashion through the third trimester of pregnancy until birth, whereupon they abruptly return to low circulating levels. The anti-autoimmune effects of estriol may also be responsible for the beneficial effects of pregnancy on MS.

Rhonda Voskuhl, M.D., has found that levels of estriol equivalent to pregnancy have potent immunomodulatory effects on MS. Dr. Voskuhl has further shown in a small number of non-pregnant female MS patients that estriol may have a therapeutic benefit by regulating the immune system and thus reducing the relapse rates, similar to the response seen in MS patients during pregnancy.

About Synthetic Biologics, Inc.

Synthetic Biologics is a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Synthetic Biologics is developing, or has partnered the development of, product candidates for the treatment of pulmonary arterial hypertension, relapsing-remitting multiple sclerosis, cognitive dysfunction in multiple sclerosis, fibromyalgia and 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," "could," "potential," "positions," "continue," "expects," "anticipates," "intends," "plans," "believe," "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 Trimesta as a treatment option for MS, the statements regarding the estimates of the potential market for oral disease-modifying therapies for MS, *the expected results of the clinical study and adequacy of funding. 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 successfully commercialize a new oral therapy for multiple sclerosis, the availability of additional financial and other resources, a failure of our clinical trial to achieve desired results, our failure to obtain FDA approval of oral Trimesta for the treatment of MS and other factors described in Synthetic Biologics' report on Form 10-K for the year ended December 31, 2010 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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