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Synthetic Biologics Provides Update on Investigator-Sponsored Phase 2b Clinical Study of SYN-010 in IBS-C Patients

ROCKVILLE, Md., Oct. 2, 2020 /PRNewswire/ --Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal ("GI") diseases in areas of high unmet need, today announced the results of a planned interim futility analysis of the investigator-sponsored Phase 2b clinical study of SYN-010 being conducted by Cedars-Sinai Medical Center ("CSMC"). Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it is unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings.

The Phase 2b study was being conducted by the Medically Associated Science and Technology ("MAST") Program at CSMC and designed to evaluate two dose strengths of oral SYN-010 (21 mg and 42 mg) in patients diagnosed with irritable bowel syndrome with constipation (IBS-C). The primary objective of the study was intended to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements ("CSBMs") during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo.

"We are grateful to the patients and Cedars-Sinai who supported this clinical trial. Although the results were disappointing for SYN-010, we remain committed to the development of new life changing medications for GI diseases" said Steven A. Shallcross, Chief Executive

Officer of Synthetic Biologics. "Looking forward, we remain focused on working with our clinical development partners to advance the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) patients, and to advance the clinical development program for SYN-020 intestinal alkaline phosphatase (IAP) in multiple potential indications."

The patent rights covering the use of SYN-010 are owned by Cedars-Sinai Medical Center and are exclusively licensed by Cedars-Sinai Medical Center to Synthetic Biologics.

About Irritable Bowel Syndrome
IBS affects an estimated 10 to 15 percent of the population, or as many as 45 million people in North America. The condition affects both men and women; however, two-thirds of diagnosed sufferers are women. It has been reported that up to 20 percent of all IBS patients have IBS-C and current FDA-approved therapies for the treatment of IBS-C, which include prescription and over-the-counter laxatives, do little to treat the underlying cause of the disease. These products provide patients with temporary relief from the symptoms of constipation by elevating the amount of water which passes through the gastrointestinal tract, but they tend to cause an IBS-C patient to swing from suffering from constipation, to suffering from diarrhea.

About SYN-010
SYN-010 is a proprietary, modified-release formulation of lovastatin lactone that is intended to reduce methane production by certain microorganisms (*M. smithii*) in the gut while minimizing disruption to the microbiome to treat an underlying cause of IBS-C. SYN-010 is intended to act primarily in the intestinal lumen while avoiding systemic absorption, thereby targeting a major cause of IBS-C, not just the symptoms. To learn more about SYN-010's unique mechanism of action, please click here.

About Synthetic Biologics, Inc.
Synthetic Biologics, Inc. (NYSE American: SYN) is a clinical-stage company leveraging the microbiome to develop therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. The Company's lead clinical candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent microbiome damage, *C. difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-010, which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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, and include statements regarding working with clinical development partners to advance the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) patients, and to advance the clinical development program for SYN-020

intestinal alkaline phosphatase (IAP) in multiple potential indications. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, a failure of additional pre-clinical studies of SYN-020 to achieve similar results to those previously achieved or to provide support for exercise of the option, a failure to receive the necessary regulatory approvals for commercialization of Synthetic Biologics' therapeutics, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004, SYN-010 and SYN-020 to be commenced or completed on time or to achieve desired results and benefits, especially in light of COVID-19, a failure of Synthetic Biologics' clinical trials to continue enrollment as expected or receive anticipated funding, a failure of Synthetic Biologics to successfully develop, market or sell its products, Synthetic Biologics' inability to maintain its material licensing agreements, or a failure by Synthetic Biologics or its strategic partners to successfully commercialize products and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2019 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. 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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