October 21, 2021

Synthetic Biologics Announces Initiation of a Phase 1 Multiple-Ascending Dose Clinical Trial for SYN-020 Intestinal Alkaline Phosphatase

Topline Data Readout Expected in Q2 2022

Phase 1 Clinical Program Intended to Support Development of SYN-020 for Multiple Indications

Including Celiac Disease, Non-Alcoholic Fatty Liver Disease, Age-Related Metabolic and Inflammatory Diseases, and Radiation Enteropathy

ROCKVILLE, Md., Oct. 21, 2021 /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 that enrollment has commenced and eight study participants were dosed in the Company's Phase 1, placebo-controlled, multiple-ascending dose (MAD) clinical study of SYN-020 intestinal alkaline phosphatase (IAP).

SYN-020 is a recombinant bovine IAP formulated for oral delivery to the small intestine. The published literature indicates that IAP functions to diminish intestinal inflammation, tighten the gut barrier to diminish "leaky gut," and promote a healthy microbiome. Despite its broad

therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacturing. Synthetic Biologics has overcome this hurdle and has the ability to produce SYN-020 at a scale and cost viable for clinical and commercial development as an oral product.

"We are excited to announce the initiation of the Phase 1 multiple-ascending dose clinical study, which is an important milestone in furthering the clinical development of SYN-020 for multiple potential indications," said Steven A. Shallcross, Chief Executive Officer and Chief Financial Officer. "SYN-020 is a promising, versatile program that we believe has enormous potential to help address a considerable need for innovative new therapies targeting disorders that stem from immune and inflammatory damage to the intestine, including celiac disease, non-alcoholic fatty liver disease (NAFLD), age-related metabolic and inflammatory diseases, and radiation enteropathy. We believe SYN-020 addresses a significant unmet market need as the total prevalent cases of celiac disease are expected to reach 4.3 million in 2023 in the U.S. alone. We look forward to announcing topline results from this study during the second quarter of 2022."

The ongoing Phase 1 placebo-controlled clinical study is intended to evaluate the safety, tolerability and biodistribution of SYN-020 upon repeated dosing in up to 32 healthy adult volunteers. The study will be divided into four sequential cohorts of eight participants, with SYN-020 (5 mg, 15, mg, 45 mg or 75 mg) given orally twice daily for 14 days. A safety review will be conducted at the end of each cohort to determine whether progression to the next higher dose cohort is permissible. A topline data readout from this clinical study is anticipated during the second quarter of 2022, pandemic conditions permitting. A previously completed Phase 1 single-ascending dose (SAD) clinical study of SYN-020 enrolled 24 healthy adult volunteers into four cohorts with SYN-020 given orally as a single dose ranging from 5 mg to 150 mg. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to study drug. No serious adverse events were reported.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is 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. The Company's lead 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 (a) microbiome damage, (b) *Clostridioides difficile* infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR), and (e) acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended 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 includes statements regarding the clinical development of SYN-020 for multiple potential

indications; SYN-020 being a promising, versatile program that has enormous potential to help address a considerable need for innovative new therapies targeting disorders that stem from immune and inflammatory damage to the intestine, including celiac disease, non-alcoholic fatty liver disease (NAFLD), age-related metabolic and inflammatory diseases, and radiation enteropathy; SYN-020 addressing a significant unmet market need and announcing topline results from the Phase 1, placebo-controlled, multiple-ascending dose (MAD) clinical study of SYN-020 intestinal alkaline phosphatase (IAP) during the second quarter of 2022. 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, Synthetic Biologics' ability to develop SYN-020 in multiple indications and address disorders that stem from immune and inflammatory damage to the intestine, the ability to announce topline resultsfrom the SYN-020 study during the second quarter of 2022, the ability to continue to comply with continued listing requirements of the NYSE American, the ability of its product candidates to demonstrate safety and effectiveness, as well as results that are consistent with prior results, Synthetic Biologics' clinical trials continuing and/or beginning enrollment as expected, a failure to receive the necessary regulatory approvals for commencement of clinical trials and commercialization of Synthetic Biologics' therapeutics, including approval of proposed trial designs, a failure of Synthetic Biologics' clinical trials, and those conducted by investigators, for SYN-004 and SYN-020 to be commenced or completed on time or to achieve desired results and benefits, 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, Synthetic Biologics' ability to achieve acceptance of its product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' products by competitors that render Synthetic Biologics' products obsolete or non-competitive, the continued maintenance and growth of Synthetic Biologics' patent estate, Synthetic Biologics becoming and remaining profitable, Synthetic Biologics' ability to obtain or maintain the capital or grants necessary to fund its research and development activities, a loss of any of Synthetic Biologics' key scientists or management personnel and other factors described in Synthetic Biologics' Form 10-K for the year ended December 31, 2020 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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