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Synthetic Biologics Announces Submission of IND Application to U.S. FDA for SYN-020 Intestinal Alkaline Phosphatase

-- Initial Indication Will Seek to Reduce Acute Intestinal Side Effects Associated with Radiation Therapy in Cancer Patients --

ROCKVILLE, Md., June 30, 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 that it submitted an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for its SYN-020 Intestinal Alkaline Phosphatase ("IAP") program. The IND application supports an initial indication of SYN-020 for the treatment of radiation enteropathy secondary to pelvic cancer therapy. Under the IND application, the Company intends to conduct a Phase 1 single ascending dose study in healthy volunteers, designed to evaluate SYN-020 for safety, tolerability, and pharmacokinetic parameters.

"This IND submission is a key milestone in the clinical development program of SYN-020, which we believe can play an important role in regulating and maintaining gastrointestinal ("GI") and microbiome health," said Steven A. Shallcross, Chief Executive and Financial Officer. "We are excited about SYN-020's potential to mitigate the intestinal damage caused by radiation therapy routinely used to treat pelvic cancers, and look forward to exploring

additional indications where the use of orally administered IAP may have a profound impact on treating and preventing age-related metabolic and inflammatory diseases."

Synthetic Biologics previously announced an agreement with Massachusetts General Hospital ("MGH") granting the Company an option for an exclusive worldwide license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases. If executed, the Company plans to use this license in the advancement of an expanded clinical development program for SYN-020.

About SYN-020 Intestinal Alkaline Phosphatase (IAP)

SYN-020 is a purified recombinant bovine IAP formulated for oral delivery to the intestines. 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 manufacture. 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. Synthetic Biologics is currently developing SYN-020 to reduce acute intestinal side effects associated with radiation therapy in patients with pelvic cancers. The Company has completed the IND-enabling nonclinical studies and early GMP manufacturing and has filed an IND application for this program.

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 conducting a Phase 1 single ascending dose study in healthy volunteers, designed to evaluate SYN-020 for safety, tolerability, and pharmacokinetic parameters, SYN-020 playing an important role in regulating and maintaining gastrointestinal and microbiome health, SYN-020's potential to mitigate the intestinal damage caused by radiation therapy routinely used to treat pelvic cancers, the use of orally administered IAP having a profound impact on treating and preventing age-related metabolic and inflammatory diseases and plans to use the license in the advancement of an expanded clinical

development program for SYN-020. 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, ability to obtain FDA clearance of the IND for the SYN-020 program, 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, the ability to enter into a license to advance an expanded clinical development program for SYN-020, 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 and SYN-010 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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