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Synthetic Biologics Enters into Exclusive Option to License Intellectual Property for Use of SYN-020 to Treat and Prevent Age-Related Metabolic and Inflammatory Diseases

ROCKVILLE, Md., May 27, 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 entered into an agreement with Massachusetts General Hospital ("MGH") granting the Company an option for an exclusive license to intellectual property and technology related to the use of intestinal alkaline phosphatase ("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, the Company's proprietary recombinant version of bovine IAP currently in pre-clinical development.

The promise of MGH's IAP research was described earlier this year in the peer-reviewed journal *JCI Insight*. A team of investigators led by Richard Hodin, MD, Chief of the Massachusetts General Hospital Division of General and Gastrointestinal Surgery and Professor of Surgery, Harvard Medical School, evaluated long-term oral supplementation of IAP, including SYN-020, in mice. IAP administration, starting at 10 months of age, slowed the microbiome changes, gut-barrier dysfunction, and gastrointestinal and systemic inflammation that normally accompany aging. Additionally, the IAP administration resulted in

improved metabolic profiles in the aged mice, diminished frailty, and extended lifespan.

Under the terms of the agreement, Synthetic Biologics is granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN-020 to treat and prevent metabolic and inflammatory diseases associated with aging.

"Multiple reported animal studies have demonstrated the high therapeutic potential of IAP to promote GI and gut microbiome health," said Steven A. Shallcross, Chief Executive and Financial Officer of Synthetic Biologics. "We are pleased to announce the expansion of our collaboration with Massachusetts General Hospital on this exciting new therapeutic approach and potential broader market opportunity for our SYN-020 IAP program. Dr. Hodin and his team's extensive research complements our current focus and expertise, which includes the development of clinical programs intended to treat and prevent GI-related diseases."

Dr. Hodin noted that the gastrointestinal tract is increasingly being recognized as a key factor in a variety of systemic diseases. "Decades of research suggest that IAP plays a major role in protecting us from the harmful effects of gut-derived mediators," he said. "I am very excited about the possibility of bringing IAP from the research bench to the bedside in the hopes of benefiting the health of many people."

About SYN-020 Intestinal Alkaline Phosphatase (IAP)

SYN-020 is a recombinant bovine Intestinal Alkaline Phosphatase (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 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 cancer patients. The Company has completed the Investigational New Drug ("IND")-enabling studies required to support the filing of an IND application for this program anticipated during the second quarter of 2020.

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 plans to use the license in the advancement of an expanded clinical development program for SYN-020, the potential of IAP to promote GI and gut microbiome health, diminish systemic inflammation, and treat age-related diseases and the possibility of bringing IAP from the research bench to the bedside in the hopes of benefiting the health of many people and the filing of an IND application for SYN-020 during the second quarter of 2020. 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 by Dr. Hodin 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 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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