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Synthetic Biologics Expands Option for an Exclusive License Agreement with Massachusetts General Hospital

Updated Agreement Includes Intellectual Property and Technology for Use of SYN-020 Intestinal Alkaline Phosphatase to Inhibit Liver Fibrosis in Select Diseases, Including Nonalcoholic Fatty Liver Disease

ROCKVILLE, Md., August 3, 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 an amendment to the Company's option for an exclusive license with Massachusetts General Hospital ("MGH") to include intellectual property ("IP") and technology related to the use of SYN-020 intestinal alkaline phosphatase ("IAP"), the Company's proprietary recombinant version of bovine IAP, to inhibit liver fibrosis in select diseases, including nonalcoholic fatty liver disease ("NAFLD").

Synthetic Biologics previously announced an option agreement with MGH to negotiate an exclusive license to IP and technology for the use of SYN-020 to prevent and treat metabolic and inflammatory diseases associated with aging. The option agreement has now been expanded to include technology developed by MGH to use SYN-020 to inhibit liver fibrosis in select diseases, including NAFLD. If executed, the license agreement would further strengthen the SYN-020 portfolio and build upon the Company's intention to pursue SYN-020 for the treatment of NAFLD, and, in particular, to slow the course of fibrosis associated with progressive disease.

"We are pleased to announce the expansion of our collaboration with Massachusetts's General Hospital and share their enthusiasm for SYN-020's potential to address diseases associated with liver fibrosis such as nonalcoholic fatty liver disease," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "We continue to view SYN-020 as a potential platform therapeutic that has a remarkable opportunity to address a considerable unmet need for innovative new therapies targeting GI disorders stemming from immune and inflammatory responses."

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

About SYN-020 Phase 1 SAD & MAD Clinical Trials

Synthetic Biologics recently announced the completion of patient dosing and observation of its Phase 1 single-ascending dose ("SAD") clinical trial of SYN-020 in 24 healthy adult volunteers. Results from this trial demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to SYN-020. No serious adverse events were reported. A second Phase 1 multiple-ascending dose ("MAD") clinical trial of SYN-020 in healthy adult volunteers is expected to commence during the third quarter of 2021 with topline results anticipated during the second quarter of 2022. Both Phase 1 SAD and MAD studies are intended to support the development of SYN-020 in multiple potential clinical indications, including celiac disease, radiation enteropathy, metabolic and inflammatory disorders associated with aging, and to inhibit fibrosis in select diseases, including NAFLD.

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 in multiple potential clinical indications, including celiac disease, nonalcoholic fatty liver disease (NAFLD), radiation enteritis, and indications to treat and prevent metabolic and inflammatory disorders associated with aging.

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 include statements regarding SYN-020's potential to address diseases associated with liver fibrosis such as nonalcoholic fatty liver disease, SYN-020 addressing a considerable unmet need for innovative new therapies targeting GI disorders stemming from immune and inflammatory responses, and commencing a second Phase 1 multiple-ascending dose ("MAD") clinical trial of SYN-020 in healthy adult volunteers during the third quarter of 2021 with topline results anticipated 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, the ability of Synthetic Biologics to successfully negotiate a license agreement with MGH, the ability of preclinical and clinical studies to provide support of SYN-020 addressing diseases associated with liver fibrosis such as nonalcoholic fatty liver disease and targeting GI disorders stemming from immune and inflammatory responses, 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-020 to be commenced or completed on time, to provide topline data when anticipated 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, 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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