Synlogic Outlines Upcoming Milestones for Clinical Programs and Unveils New Preclinical Pipeline Programs

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– First subject treated in SYNB1891 immuno-oncology study, data from monotherapy arm expected in 2020 –

– Expansion of pipeline with new preclinical programs in secondary hyperoxaluria and maple syrup urine disease (MSUD) –

– Phase 2 clinical trial of solid formulation of SYNB1618 in patients with phenylketonuria expected to begin in 1H2020 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 9, 2020-- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today outlined key objectives and anticipated milestones for 2020 and provided an overview of recent progress.

"In 2020 we look forward to advancing our platform and our growing development stage pipeline of Synthetic Biotic ™ medicines - advancing our phenylketonuria program and additional oral metabolic programs that build on the critical capabilities we have established in development and manufacturing, as well as advancing our first clinical program in oncology," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "We believe that Synthetic Biotic medicines have potential across multiple diseases and conditions. Our expanded collaboration with Ginkgo Bioworks, strong balance-sheet and solid momentum out of our discovery and development efforts position us well to execute on our near-term clinical plans."

2020 Goals and Milestones
Clinical Programs

- ***SYNB1618:*** SYNB1618 is an orally delivered, Synthetic Biotic medicine designed to consume phenylalanine (Phe) in the gastrointestinal (GI) tract for the treatment of phenylketonuria (PKU) in patients regardless of age or disease type.
    - In the first half of 2020, Synlogic expects to initiate a Phase 2 clinical trial to evaluate the Phe-lowering potential of its solid formulation of SYNB1618 in patients with PKU. In addition, the study is expected to provide valuable information to validate predictive mathematical and preclinical modeling.
    - Strain development and optimization work is being carried out under Synlogic's 2019 research and development agreement with Ginkgo Bioworks.
- ***SYNB1891:*** Synlogic's first clinical immuno-oncology (IO) program, SYNB1891, is an intratumorally delivered Synthetic Biotic medicine designed to produce a STING agonist and act as a dual innate immune activator for the treatment of refractory solid tumors and lymphoma.
    - SYNB1891 is being evaluated as a monotherapy in a Phase 1 open-label, multicenter, dose escalation clinical trial (NCT04167137) in patients with refractory solid tumors and lymphoma. Three U.S. sites have been activated to enroll and the first subject has been dosed. Synlogic expects to have data from the monotherapy arm of this study in 2020.
    - After establishing a maximum tolerated dose (MTD) for SYNB1891, Synlogic will initiate a second arm of the trial in which subjects will receive escalating dose levels of SYNB1891 in combination with a fixed dose of the checkpoint inhibitor, atezolizumab (Tecentriq®), to establish a recommended dose for the combination regimen.
- ***Pre-clinical data and early pipeline programs:***
    - Synlogic has advanced two new preclinical programs onto its development pipeline, for the treatment of secondary hyperoxaluria and MSUD, respectively. Strain development and optimization work is being carried out under Synlogic's 2019 research and development agreement with Ginkgo Bioworks.
    - Synlogic expects to publish and present data at major scientific and medical meetings throughout the year demonstrating the breadth and potential of its Synthetic Biotic platform.

Corporate

- Synlogic ended the third quarter of 2019 with $138.7 million in cash, cash equivalents and short- and long-term investments and expects that this will fund Company operations through 2021 under its current plan.
- The Company will continue to explore additional strategic opportunities to maximize the potential of its Synthetic Biotic platform.

2019 Accomplishments and Highlights
Clinical Pipeline

- ***SYNB1618***
  - Presentation of positive data from Phase 1/2a study of SYNB1618 in patients with phenylketonuria (PKU) using the liquid formulation as well as modeling work to estimate target dosing of SYNB1618. SYNB1618 was well tolerated in healthy volunteers and patients with PKU and the data demonstrated equivalent SYNB1618-dependent Phe-consumption from the GI tract in both populations.
  - Development of a solid oral formulation of SYNB1618 that is stable at room temperature. Synlogic executed a bridging study in healthy volunteers of a new solid oral formulation to identify an MTD that could be used to evaluate lowering of blood Phe levels in PKU patients based on Synlogic's modeling data. Data from this study will be presented at an appropriate medical meeting in 2020. Synlogic expects to advance SYNB1618 into a Phase 2 study in patients in the first half of 2020.
- ***SYNB1891:***
  - Initiation of a Phase 1 open-label, multicenter, dose escalation trial of its STING-agonist producing bacterial strain, SYNB1891, for the treatment of refractory solid tumors and lymphoma.

Corporate

- Establishment of a collaboration with Ginkgo Bioworks that provides expanded synthetic biology capabilities and strengthened Synlogic's balance sheet. In June 2019, Synlogic and Ginkgo entered into a long-term strategic platform collaboration. Under the agreement Ginkgo invested $80.0 million in Synlogic at a premium to market. Synlogic is using Ginkgo's cell programming platform for building and testing microbial strains to accelerate progression of early preclinical leads to drug candidates optimized for further clinical development. Under the terms of the agreement, Synlogic paid $30.0 million to Ginkgo for synthetic biology services and has exclusive rights to any Synthetic Biotic medicines that it develops as part of the collaboration and to intellectual property covering such products.
- Strengthened Synlogic's executive leadership with the following appointments:
  - Richard Riese, M.D. Ph.D., joined Synlogic in September 2019 as chief medical officer assuming responsibilities for all clinical and regulatory functions from current president and CEO, Aoife Brennan. Prior to joining Synlogic, he served as Vice President, Clinical Development at Alnylam Pharmaceuticals where he led clinical development projects in several areas across Alnylam's rare disease portfolio.
  - Gregg Beloff was appointed as Synlogic's interim chief financial officer, in October 2019. Mr. Beloff has more than 20 years of experience in the life sciences industry and brings significant expertise in operational management, strategic planning, corporate and business development, fundraising and mergers and acquisitions.
  - Patricia Hurter, Ph.D., chief executive officer of Lyndra Therapeutics, was appointed to the Synlogic board of directors in January 2019. Dr. Hurter previously served as Senior Vice President at Vertex. Prior to joining Vertex, Dr. Hurter was Director, Formulation Design and Characterization for Merck.
- Established a clinical collaboration with Roche that enables evaluation of SYNB1891, in combination with atezolizumab in the second arm of Synlogic's ongoing Phase 1 study in patients with advanced solid tumors and lymphoma.
- Established GMP manufacturing capabilities and manufactured solid and liquid formulations of clinical trial material for its oral and intra-tumoral programs, respectively.
- Advanced collaboration with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease resulting in payment to Synlogic of a $2.5 million milestone in March 2019.
- Published first in human clinical data of a Synthetic Biotic medicine (SYNB1020) as well as preclinical data from the program in *Science Translational Medicine*.

About Synlogic

Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotic medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer beneficial microbes to perform or deliver critical functions missing or damaged due to disease. When delivered orally, Synthetic Biotic medicines are designed to function in the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect, with the potential to significantly improve symptoms of disease for affected patients. The Company's lead program in this area, SYNB1618, targets PKU. In addition, the Company is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including inflammatory and immune disorders, and cancer. Synlogic's first immuno-oncology program, SYNB1891, is in clinical development for the treatment of solid tumors and lymphoma. Synlogic is collaborating with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please visit www.synlogictx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995, including statements regarding Synlogic's plans and expectations for the development of SYNB1618 and SYNB1891. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Synlogic may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the potential of Synlogic's platform to develop therapeutics to address a wide range of diseases including: cancer, inborn errors of metabolism, and inflammatory and immune disorders; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; and the expected timing of Synlogic's clinical trials and availability of clinical trial data. Actual results could differ materially from those contained in any forward-looking statement

as a result of various factors, including: the uncertainties inherent in the preclinical and clinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Synlogic's filings with the SEC. The forward-looking statements contained in this press release reflect Synlogic's current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic's view as of any date subsequent to the date hereof.

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Source: Synlogic, Inc.

MEDIA CONTACT:
Caroline Rufo, Ph.D.
MacDougall
Phone: 781-235-3060
Email: crufo@macbiocom.com

INVESTOR CONTACT:
Elizabeth Wolffe, Ph.D.
Synlogic, Inc.
Phone: 617-207-5509
Email: liz@synlogictx.com