Synlogic Bridging Study Data with Solid Oral Formulation of SYNB1618, a Synthetic Biotic Approach to Treat Phenylketonuria, Demonstrate Improved Tolerability over Early Liquid Formulation and Guide to Next Stage of Clinical Development

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– Company expects to initiate Phase 2 clinical trial in patients with phenylketonuria in 1H 2020 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 11, 2019-- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today announced that data from the Company's bridging study in healthy volunteers of a solid formulation of SYNB1618 support its continued development for the treatment of phenylketonuria (PKU). Synlogic expects to initiate a Phase 2 clinical trial of SYNB1618 to evaluate its potential to lower blood phenylalanine (Phe) in patients with PKU in the first half of 2020.

"We are pleased with the results of this study, which have allowed us to select a maximum tolerated dose of the solid, oral formulation of SYNB1618 to move into a Phase 2 clinical trial," said Richard Riese, M.D., Ph.D., Synlogic's chief medical officer. "Incorporating what we have learned, we expect to initiate a clinical trial in patients with PKU that will assess the Phe-lowering potential of SYNB1618 and confirm our modeling. We look forward to presenting the full data set from our bridging study at an appropriate scientific meeting, and to providing more detail regarding the Phase 2 clinical trial design at a later date."

The bridging study's primary objectives were to evaluate safety and tolerability of an optimized manufacturing process and solid formulation of SYNB1618 and its Phe-consuming activity in healthy volunteers, as determined by production of previously identified biomarkers. In addition to identifying a maximum tolerated dose of 2×10^{12} live cells (5.3×10^{11} colony forming units, or CFUs), the study demonstrated that a dose ramp improved SYNB1618 tolerability and that pH buffering was required for maximum Phe-consuming activity of the strain.

"Development of a solid oral formulation of a Synthetic Biotic medicine that is stable at room temperature and can be administered at home, is a major achievement for our platform and a meaningful innovation for SYNB1618. We are a step closer to providing a new therapeutic option that is suitable for all patients with PKU regardless of age or disease type," said Aoife Brennan, M.B., B.Ch., Synlogic's president and chief executive officer. "Data obtained in this study provide valuable information as we continue to advance SYNB1618 and other orally administered Synthetic Biotic medicines to address additional indications with high unmet medical need."

About Phenylketonuria (PKU)
PKU is caused by a defect in the gene encoding phenylalanine hydroxylase (PAH), a liver enzyme that metabolizes Phe. Phe is an essential amino acid that enters the body as a component of dietary protein and can be toxic if it accumulates in the blood and brain. Current disease management of PKU involves strict dietary protein restriction with the consumption of Phe-free protein supplements. Life-long Phe control is challenging due to the highly restrictive nature of the diet and patients typically experience worsening neuropsychological and cognitive function depending on the severity of their genetic mutation and their treatment compliance. PKU is diagnosed at birth, and the National PKU Alliance estimates that there are approximately 16,500 people living with the disorder in the U.S.

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 probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The Company's lead program, SYNB1618, targets PKU. When delivered orally, Synthetic Biotic medicines can act from 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. 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. 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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