Synlogic Presents Data Describing a Solid Oral Formulation Process for Synthetic Biotic™ Medicine SYNB1618 for the Treatment of PKU at the 22nd Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT)

April 30, 2019

- Synlogic's robust and reproducible lyophilization process provides a solid formulation of SYNB1618 with improved quality attributes, stability and minimal loss of viability compared to liquid formulation -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 30, 2019-- Synlogic, Inc., (Nasdaq: SYBX) a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today announced that data demonstrating its development of a robust and reproducible process to generate a solid oral formulation of its Synthetic Bioticmedicine, SYNB1618, are being presented today at the 22nd Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT). Synlogic is developing SYNB1618 for the treatment of phenylketonuria (PKU).

"We have developed a process to generate a solid formulation of SYNB1618 for oral use that makes it more patient-friendly and provides a stability profile suitable for eventual commercialization," said Antoine Awad, Synlogic's head of technical operations. "The data presented at the ASGCT meeting demonstrate that we can generate a solid preparation of SYNB1618 with minimal impact on cell viability and activity and improved quality attributes compared to the liquid formulation that is being used in our ongoing clinical trial. We plan to apply our solid formulation expertise across our pipeline products."

"We recognized that development of a solid formulation process was critical to advancement of our orally administered Synthetic Biotic medicines through clinical development toward commercialization," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "We made a strategic decision to develop this process in parallel with clinical testing of an early liquid formulation in our first two programs. Our clinical experience with the liquid formulation has enabled the rapid achievement of proof-of-mechanism, as well as an understanding of the translation of the medicines' activity from preclinical models to humans. Following the readout from our Phase 1/2a study in patients with PKU later this year, we will be integrating the solid oral formulation into the SYNB1618 development program."

SYNB1618 is designed to function in the gastrointestinal (GI) tract and has been engineered with two enzyme pathways to consume phenylalanine (Phe), an essential amino acid that can accumulate to harmful levels in patients with PKU with severe health consequences. SYNB1618 metabolizes Phe to harmless compounds including trans-cinnamic acid (TCA) in the blood which is further metabolized in the liver and excreted as hippuric acid (HA) in the urine. TCA and HA, therefore, represent specific biomarkers of SYNB1618 activity. Synlogic has conducted a Phase 1 /2a study in healthy volunteers who were treated with an early formulation of SYNB1618 (frozen liquid) and is currently evaluating the same formulation in single and multiple dose expansion cohorts in patients with PKU, with data expected mid-2019. Dose-dependent production of TCA in the serum and HA in the urine were observed in SYNB1618-treated but not placebo-treated healthy subjects demonstrating proof of mechanism. The data were announced in September 2018 and confirmed preclinical data published earlier in *Nature Biotechnology*. In future clinical studies, Synlogic plans to use a solid formulation of SYNB1618 which is more patient-friendly and will enable outpatient clinical trials of longer duration that will be required to demonstrate efficacy.

As described in the ASGCT presentation, Synlogic's scientists have successfully developed a process that demonstrates:

- batch to batch reproducibility in cell viability and activity at the 30L production scale
- improved physical quality attributes of the product; and
- a solid formulation that:
    - is similarly active to frozen liquid in terms of consumption of Phe or production of TCA/HA in an *in vitro* gut simulation model and *in vivo* in non-human primates and a mouse model of disease
    - in initial studies is stable for >90 days at 2-8˚C and >30 days at room temperature (Synlogic intends to generate shelf-life data over two years).

As a solid oral formulation with improved stability and convenience SYNB1618 has potential as a new therapy for managing blood Phe levels in patients with PKU.

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. Synthetic Biotic medicines are designed to act locally and have a systemic effect to address disease in patients. Synlogic's two lead programs, SYNB1020 and SYNB1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYNB1891 as an intratumorally-administered Synthetic Biotic medicine for the treatment of cancer. In addition, the company is leveraging the broad potential of its platform to create additional Synthetic Biotic medicines for the treatment of liver disease, as well as inflammatory and immune disorders including Synlogic's collaboration 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. 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: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic’s technology to treat hyperammonemia, phenylketonuria and cancer. 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 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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