Synlogic Announces Initiation of Phase 1 Study of SYNB1934, a Next-Generation Strain for the Treatment of Phenylketonuria (PKU)

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- SYNB1934, an evolved strain of SYNB1618, has the potential to provide increased benefit to patients living with PKU -

- SYNB1934 Phase 1 Study to evaluate safety, tolerability, and head-to-head comparison of biomarkers of Phe-consumption between SYNB1934 and SYNB1618 -

- SYNB1618 Phase 2 Study in patients with PKU ongoing with data readout expected in 2H 2021 -

CAMBRIDGE, Mass., July 15, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today announced that it has initiated the Phase 1 clinical trial of SYNB1934, an investigational Synthetic Biotic™ medicine for the treatment of Phenylketonuria (PKU).

"We are delighted to have so quickly advanced SYNB1934 into the clinic, strengthening our PKU portfolio and our potential to provide a meaningful new therapeutic option for patients living with PKU," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "We are on track to report results from our Phase 2 clinical trial of SYNB1618 in the second half of 2021 and look forward to providing additional updates as we advance our PKU portfolio."

"SYNB1618 and SYNB1934 are orally administered Synthetic Biotic medicines intended to address the needs of PKU patients of all age groups and genotypes through the consumption of Phe in the gastrointestinal tract," said Richard Riese, M.D., Synlogic's Chief Medical Officer. "Our orally available and fully reversible Synthetic Biotic medicines have the potential to lower blood Phe levels, and potentially enable the consumption of more natural dietary protein. We aspire to bring forward the most compelling medicine possible to meet the needs of the significant number of patients who do not benefit from, or do not tolerate, existing therapies."

SYNB1934 is a strain that has been evolved from SYNB1618, which is currently being evaluated in a Phase 2 clinical study. SYNB1934 has the potential to provide increased phenylalanine (Phe) lowering efficacy for patients living with PKU. Preclinical *in vivo* and *in vitro* studies demonstrated a greater than 2-fold improvement in the ability of SYNB1934 to consume and break down Phe compared to SYNB1618, based on production of Phe metabolites.

The Phase 1 multiple ascending dose study of SYNB1934 will evaluate the safety, tolerability and Phe consumption activity of SYNB1934, including a head-to-head comparison with SYNB1618 in healthy volunteers using biomarkers of Phe consumption. Based on the data from the head-to-head comparison, as well as results of the ongoing Phase 2 study of SYNB1618 in patients with PKU, Synlogic plans to select one therapeutic strain for late stage development. Data from the Phase 1 study is expected by the end of 2021.

Data on the solid oral formulation of SYNB1618 was presented at the American College of Medical Genetics meeting in April 2021, and data on the development of SYNB1934 was presented at the Synthetic Biology: Engineering, Evolution & Design (SEED) conference in June 2021.

Patients can learn more about the SynPheny-1 study (NCT04534842) by visiting https://pkuresearchstudy.com. More information about Synlogic's programs and pipeline can be found at https://www.synlogictx.com.

About PKU

Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down Phe, an amino acid that is commonly found in many foods. Left untreated, high levels of Phe become toxic and can lead to serious neurological and neuropsychological problems affecting the way a person thinks, feels, and acts. Due to the seriousness of these symptoms, infants are screened at birth in many countries to ensure early diagnosis and treatment to avoid intellectual disability and other complications.

About Synlogic

Synlogic™ is bringing the transformative potential of synthetic biology to medicine. With a premiere synthetic biology platform that leverages a reproducible, modular approach to microbial engineering, Synlogic designs Synthetic Biotic medicines that target validated underlying biology to treat disease in new ways. Synlogic's proprietary pipeline includes Synthetic Biotics for the treatment of metabolic disorders including Phenylketonuria (PKU) and Enteric Hyperoxaluria. The company is also building a portfolio of partner-able assets in immunology and oncology.

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, clinical development plans, 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, metabolic diseases, 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; 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 clinical and 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 Securities and Exchange Commission.

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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