Synlogic Presents Data Demonstrating Reductions in Plasma Phenylalanine Levels in Patients with Phenylketonuria Treated with SYNB1618

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Interim data from Phase 2 SynPheny-1 trial featured in late-breaking oral presentation during 14th International Congress of Inborn Errors of Metabolism Meeting

Data demonstrate ability of SYNB1618 to consume phenylalanine from the GI tract

Synlogic also presents two posters with additional data on next-generation Synthetic Biotic SYNB1934

CAMBRIDGE, Mass., Nov. 22, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage company bringing the transformative potential of synthetic biology to medicine, today announced presentation of interim data from the company's Phase 2 SynPheny-1 clinical trial showing that treatment with the investigational Synthetic Biotic™ medicine SYNB1618 resulted in significant reductions in plasma phenylalanine (Phe) levels in patients with phenylketonuria (PKU). Results were presented today by Dr. Jerry Vockley, MD, PhD in a late-breaking oral presentation during the International Congress of Inborn Errors of Metabolism Meeting in Sydney, Australia.

In an interim analysis of eight patients, treatment with SYNB1618 was associated with a 40% reduction in D5-Phe absorption after a meal challenge, a 20% reduction in mean fasting plasma Phe across all subjects, and a >250 µM mean reduction in fasting plasma Phe among responder subjects. Treatment with SYNB1618 was also generally well tolerated, with no serious adverse events and a tolerability profile consistent with results from previous Phase 1 studies.

"PKU remains a devastating disease on multiple dimensions. Despite approved medicines, many people living with PKU remain in significant need of a treatment option that can work for them," said Dr. Vockley, Chief of Medical Genetics at UPMC Children's Hospital of Pittsburgh and lead investigator on the study. "These data provide evidence that SYNB1618 can reduce plasma Phe levels in PKU patients with an oral therapy that works locally in the gastrointestinal tract."

Synlogic also presented data for SYNB1934, the company's next-generation Synthetic Biotic therapy for the treatment of PKU, in poster presentations during the ICIEM meeting. These presentations demonstrated optimization of the Phe-degrading PAL enzyme contained within SYNB1934 and enhanced Phe consumption activity of SYNB1934 relative to SYNB1618 in healthy volunteers. Synlogic has added an additional arm to the ongoing Phase 2 Synpheny-1 trial to include a cohort of PKU patients treated with SYNB1934.

"These strong results from our Phase 2 study of SYNB1618, along with our emerging preclinical and clinical dataset for SYNB1934 demonstrating an approximate doubling in biomarkers of Phe consumption, provide further validation of the potential for Synthetic Biotic therapies to make a meaningful impact on the lives of patients living with PKU," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "We look forward to building on these positive interim findings with additional data from Synpheny-1 including both SYNB1618 and SYNB1934 in the first half of 2022 as we advance our PKU program toward an expected Phase 3 study start."

About Phenylketonuria

Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down Phe, an amino acid 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 reduce the risk of intellectual disability and other complications.

About SYNB1618 and SYNB1934

SYNB1618 and SYNB1934 are orally administered Synthetic Biotic™ medicines being developed as potential treatments for phenylketonuria (PKU). They are engineered strains of the microorganism E. coli Nissle that encodes phenylalanine ammonia lyase (PAL), an enzyme that breaks down Phe. They are intended to address the needs of patients of all age groups through the consumption of Phe in the gastrointestinal tract, which has the potential to lower blood Phe levels and enable the consumption of more natural protein in the diet.

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), enteric hyperoxaluria, and homocystinuria. The company is also building a portfolio of partner-able assets in immunology.

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, and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; 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 of SYNB1618 or SYNB1934, 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 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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