



## Synlogic Announces Progress Toward 2022 Clinical Milestones and Participation at Upcoming Investor Conferences

*- On track to initiate Phase 3 for treatment of phenylketonuria (PKU) in H2 2022 -*

*- Additional milestones include multiple clinical read-outs across programs including enteric hyperoxaluria and homocystinuria (HCU) during 2022 -*

CAMBRIDGE, Mass., Jan. 6 /PRNewswire/ -- Synlogic, Inc. ([Nasdaq: SYBX](#)), a clinical-stage biotechnology company developing medicines for metabolic and immunological diseases through its proprietary approach to synthetic biology, today provided an update on progress towards multiple 2022 clinical milestones.

"The past year was transformational for Synlogic as we achieved clinical proof of concept in phenylketonuria (PKU), a disease that causes tremendous burden to all of those affected. Current treatments leave a need for a safe, effective, and convenient oral treatment option and we are thrilled to be on track to begin the pivotal Phase 3 program in the second half of 2022," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "Last year brought additional progress, including clinical proof of mechanism in enteric hyperoxaluria, a research collaboration with Roche and a new clinical candidate for homocystinuria (HCU) developed in partnership with Gingko Bioworks. Our plans for 2022 will build on this progress with multiple clinical data readouts expected across our programs."

### Clinical Programs and Anticipated 2022 Milestones

In rare metabolic diseases, Synlogic reported positive interim data from the Phase 2 SynPheny-1 study in patients with PKU with its lead drug candidate, SYNB1618, in September 2021. PKU is an inherited inborn error of metabolism that results in significant disease burden, with current options leaving the majority of PKU patients either untreated or in need of better treatment options. In November, Synlogic announced SYNB1353, a drug candidate designed to consume methionine in the gastrointestinal tract developed through the Company's research collaboration with Gingko Bioworks, for the treatment of HCU, an inherited inborn error of metabolism that, like PKU, results in significant disease burden with limitations in today's treatment options.

In April 2021, Synlogic reported proof-of-mechanism with robust dose-dependent urinary oxalate lowering for SYNB8802, which is being developed for the treatment of enteric hyperoxaluria, a progressive, chronic disease characterized by recurrent kidney stones and risk of progressive kidney damage.

Synlogic's research collaboration with Roche to develop a Synthetic Biotic medicine for the treatment of inflammatory bowel disease is continuing with the potential for additional research milestones during 2022. Synlogic and Ginkgo are also advancing their research collaboration to include additional, undisclosed preclinical assets.

Expected clinical milestones across these programs include:

#### **Rare Metabolic Diseases**

- SYNB1618 and SYNB1934 for PKU
  - Data from the Phase 2 SynPheny-1 study H1 2022
  - Phase 3 trial initiation H2 2022
- SYNB1353 for HCU
  - Data from Phase 1 trial in healthy volunteers H2 2022

#### **Enteric Hyperoxaluria**

- SYNB8802 for enteric hyperoxaluria
  - Proof of concept 2022

#### **Upcoming Industry and Banking Conferences**

Synlogic will participate in the banking and industry conferences listed below in early 2022. Recorded presentations will be available at <https://investor.synlogictx.com>.

- **H.C. Wainwright BIOCONNECT Virtual Conference.** Synlogic will present a corporate update at the H.C. Wainwright BIOCONNECT Virtual Conference taking place from January 10-13, 2022. The recorded presentation will be available beginning Monday, January 10, 2022, at 7:00 a.m. Eastern Time.
- **BIO CEO & Investor Conference.** Synlogic will attend and present at the 2022 BIO CEO & Investor Conference taking place virtually and in-person from February 14-17, 2022, in New York City.
- **11th Annual SVB Leerink Global Healthcare Conference.** Synlogic will attend and present at the 11th Annual SVB Leerink Global Healthcare Conference taking place virtually from February 14-18, 2022.

#### **About Synlogic**

Synlogic is a clinical-stage biotechnology company developing medicines through its proprietary approach to synthetic biology. Synlogic's pipeline includes its lead program in phenylketonuria (PKU), which has demonstrated proof of concept with plans to start a pivotal, Phase 3 study in the second half of 2022, and additional novel drug candidates designed to treat homocystinuria (HCU) and enteric hyperoxaluria. The rapid advancement of these potential biotherapeutics, called Synthetic Biotics, has been enabled by Synlogic's proprietary, reproducible, target-specific drug design. Synlogic uses precision genetic engineering of well-characterized probiotics to exert localized activity for therapeutic benefit, with a focus on metabolic and immunologic diseases. Synlogic is also working with Roche in a research collaboration focused on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease and with Ginkgo Bioworks to include additional undisclosed preclinical assets, combining Synlogic's approach to Synthetic Biotics with Ginkgo's Codebase and Foundry services. For additional information visit [www.synlogictx.com](http://www.synlogictx.com).

## About SYNB1618 and SYNB1934

SYNB1618 and SYNB1934 are orally administered, non-systemically absorbed drug candidates being studied as potential treatments for phenylketonuria (PKU), a genetic disease caused by potentially neurotoxic levels of the amino acid phenylalanine (Phe). Treatment options for PKU are currently limited due to efficacy and safety, with an estimated 80% of US patients remaining in need of treatment, and many of those who are treated in need of additional Phe-lowering. Synlogic designed drug candidates to reduce levels of Phe in people with PKU using precision genetic engineering of the well-characterized probiotic *E. coli* Nissle. Findings to date support the potential for an efficacious, safe, convenient, and flexible treatment option for PKU, and SYNB1618 has received both Orphan Drug and Fast Track designations by the US Food and Drug Administration (FDA). Both drug candidates are being studied in the Phase 2 Synpheny-1 study, with data expected in H1 2022, and initiation of the Phase 3 program to begin in H2 2022.

## About SYNB1353

SYNB1353 is a novel orally administered, non-systemically absorbed drug candidate designed to consume methionine in the gastrointestinal tract thereby lowering homocysteine levels in patients with homocystinuria (HCU). HCU is an inherited disorder characterized by high levels of homocysteine and risks including thromboembolism, lens dislocation, skeletal abnormalities, developmental delay, and intellectual disability. Treatment options for HCU are currently limited due to efficacy and tolerability. SYNB1353 is currently in IND-enabling studies and was developed as part of a research collaboration with Synlogic and Gingko Bioworks. Synlogic holds worldwide development and commercialization rights to SYNB1353, which is expected to begin clinical development and report Phase 1 data in healthy volunteers in H2 2022.

## About SYNB8802

SYNB8802 is a novel, orally administered, non-systemically absorbed drug candidate being developed for the treatment of enteric hyperoxaluria, a chronic, progressive disease characterized by high levels of urinary oxalate, the leading cause of recurrent kidney stones. Oxalate crystals can damage kidneys, leading to chronic kidney disease and end-stage renal disease (ESRD). SYNB8802 was designed using precision genetic engineering of the well-characterized probiotic *E. coli* Nissle to lower urinary oxalate levels by consuming oxalate throughout the GI tract. In 2021, Synlogic reported positive proof-of-mechanism for SYNB8802 from a Phase 1b study that demonstrated lowering of urinary and fecal oxalate levels in healthy volunteers with diet-induced hyperoxaluria. Data from a proof-of-concept study assessing the lowering of urinary oxalate in patients who have undergone Roux-en-Y gastric bypass surgery is expected in 2022.

## 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 approach to Synthetic Biotics to develop therapeutics to address a wide range of

diseases including: inborn errors of metabolism, and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; the future clinical development of Synthetic Biotics; 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, SYNB1934, SYNB1353 and SYNB8802 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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