Synlogic and Ginkgo Bioworks Announce Investigational Synthetic Biotic Medicine for the Treatment of Homocystinuria

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Synlogic and Ginkgo collaboration generates clinical candidate SYNB1353 using Synlogic's proprietary Synthetic Biotic platform and Ginkgo Codebase

SYNB1353 is the first investigational medicine developed from Ginkgo's platform to advance to IND-enabling studies

Synlogic to present preclinical data on SYNB1353 at the upcoming International Congress of Inborn Errors of Metabolism 2021 meeting

CAMBRIDGE, Mass. and BOSTON, Nov. 9, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage company bringing the transformative potential of synthetic biology to medicine, and Ginkgo Bioworks (NYSE: DNA), the leading horizontal platform for cell programming, today announced the nomination of SYNB1353, an investigational Synthetic Biotic™ medicine for the treatment of homocystinuria (HCU). SYNB1353 is the first product developed through a research collaboration between Synlogic and Ginkgo and the first investigational medicine developed on Ginkgo's platform to enter IND-enabling studies. Synlogic expects to file an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for SYNB1353 and begin clinical development in 2022.

"SYNB1353 is an exciting addition to the Synlogic pipeline aimed at helping patients living with diseases of methionine metabolism. Starting with HCU, we see these diseases as the natural next step in our metabolic portfolio after the successful proof of concept of synthetic biotics in phenylketonuria announced earlier this year. This program builds on what we have learned from our metabolic program work to date, with the potential to provide a new therapeutic option to reduce the devastating consequences of these diseases," said Dr. David Hava, chief scientific officer at Synlogic. "The advancement of SYNB1353 illustrates both the potential of our Synthetic Biotic platform to generate new therapeutic candidates and the value of our collaboration with Ginkgo."

"We're so honored to be able to support Synlogic in building their incredible platform to provide potential new treatment options for people living with difficult to treat diseases," said Patrick Boyle, head of codebase at Ginkgo. "This is just the beginning for a new generation of medicines unlocked by the power of synthetic biology, and we're excited to be working with Synlogic on multiple additional preclinical programs in their portfolio."

HCU is an inherited disorder caused by the loss of function of cystathionine beta-synthase, which results in excessive accumulation of homocysteine and its metabolites in the blood and urine. Patients develop multisystem clinical manifestations, including ectopia lentis, bone defects, intellectual disability, and life-threatening thromboembolisms. Many patients are required to comply with a rigid methionine-restricted diet and have few treatment options available.

SYNB1353 is an engineered strain of the probiotic bacteria E. coli Nissle (EcN) which consumes methionine within the gastrointestinal tract, preventing methionine absorption and conversion to homocysteine in plasma. During the collaboration, SYNB1353 was designed using Ginkgo's proprietary codebase. The high-throughput testing of codebase libraries by Ginkgo enabled SYNB1353 to advance from preclinical proof-of-concept to candidate strain in the space of a year.

Researchers from Synlogic and Ginkgo will present preclinical data supporting advancement of SYNB1353 into IND-enabling studies at the International Congress of Inborn Errors of Metabolism 2021. The poster, *Development of an Investigational Methionine-consuming Synthetic Biotic Medicine (SYNB1353) for the Treatment of Homocystinuria*, will be available at the International Congress of Inborn Errors of Metabolism 2021 on November 21-23, 2021 in Sydney, Australia.

Following the event, the poster will also be available to view on www.synlogictx.com.

About SYNB1353
SYNB1353 is a novel medicine in development for the treatment of diseases of methionine metabolism including homocystinuria (HCU). SYNB1353 is designed to lower plasma homocysteine levels by metabolizing methionine, a precursor to homocysteine, in the gastrointestinal (GI) tract. SYNB1353 was developed using Synlogic's Synthetic Biotic platform incorporating components of Ginkgo Bioworks' codebase. Synlogic holds worldwide development and commercialization rights to SYNB1353.

About Synlogic
Synlogic is bringing the transformative potential of synthetic biology to medicine. With a premier 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. Learn more about Synlogic's programs and pipeline by visiting https://www.synlogictx.com/.

About Ginkgo Bioworks
Ginkgo is building a platform to enable customers to program cells as easily as we can program computers. The company's platform is enabling biotechnology applications across diverse markets, from food and agriculture to industrial chemicals to pharmaceuticals. Ginkgo has also actively supported a number of COVID-19 response efforts, including K-12 pooled testing, vaccine manufacturing optimization and therapeutics discovery. For more information, visit www.ginkgobioworks.com.

About the Synlogic - Ginkgo Collaboration
Formed in 2019, the Synlogic - Ginkgo collaboration is a five year, $30M strategic platform collaboration which accelerates expansion and development of Synlogic's pipeline of Synthetic Biotic medicines using Ginkgo's cell programming platform, including Ginkgo's foundry and codebase. Synlogic has exclusive rights to any Synthetic Biotic medicines that it develops as part of the collaboration and to certain intellectual property covering such products.

Forward-Looking Statements of Synlogic, Inc.
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, diseases of methionine 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 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.

Forward-Looking Statements of Ginkgo Bioworks
This press release contains certain forward-looking statements within the meaning of the federal securities laws, including statements regarding the potential success of the partnership and Ginkgo's cell programming platform. These forward-looking statements generally are identified by the words "believe," "project," "potential," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this document, including but not limited to: (i) the effect of the business combination with Soaring Eagle Acquisition Corp. ("Soaring Eagle") on Ginkgo's business relationships, performance, and business generally, (ii) risks that the business combination disrupts current plans of Ginkgo and potential difficulties in Ginkgo's employee retention, (iii) the outcome of any legal proceedings that may be instituted against Ginkgo related to its business combination with Soaring Eagle, (iv) volatility in the price of Ginkgo's securities now that it is a public company due to a variety of factors, including changes in the competitive and highly regulated industries in which Ginkgo plans to operate, variations in performance across competitors, changes in laws and regulations affecting Ginkgo's business and changes in the combined capital structure, (v) the ability to implement business plans, forecasts, and other expectations after the completion of the business combination, and identify and realize additional opportunities, and (vi) the risk of downturns in demand for products using synthetic biology. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of Ginkgo's current report on Form 8-K filed with the U.S. Securities and Exchange Commission (the "SEC") on September 20, 2021 and other documents filed by Ginkgo from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and Ginkgo assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Ginkgo does not give any assurance that it will achieve its expectations.

SYNLOGIC INVESTOR CONTACT:
Daniel Rosan
Synlogic, Inc.
617-401-9152
dan.rosan@synlogictx.com

SYNLOGIC MEDIA CONTACT:
Jenna Urban

Berry & Company Public Relations
212-253-8881
jurban@berrypr.com

GINKGO BIOWORKS INVESTOR CONTACT:
investors@ginkgobioworks.com

GINKGO BIOWORKS MEDIA CONTACT:
press@ginkgobioworks.com

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