Synlogic Granted FDA Fast Track Designation for SYNB1353 for the Treatment of Homocystinuria (HCU)

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CAMBRIDGE, Mass., Aug. 23, 2022 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company developing medicines for metabolic and immunological diseases through its proprietary approach to synthetic biology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SYNB1353 for the potential treatment of homocystinuria (HCU).

The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. To qualify, available clinical and non-clinical data need to demonstrate meaningful therapeutic potential. The benefits of Fast Track designation include opportunities for frequent meetings with the FDA to discuss trial design, development plans and data needed to support drug approval, as well as the ability to submit a registrational filing for approval on a rolling basis, and eligibility for priority review, if relevant criteria are met. SYNB1353, an orally-administered, non-systemically absorbed drug candidate designed to consume methionine in order to lower homocysteine levels, is currently being evaluated in a Phase 1 study in healthy volunteers.

"The FDA's Fast Track designation reinforces our conviction for the urgent need for new treatments for HCU as well as the promising non-clinical data we have generated in the program to date," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "We look forward to sharing additional data from the program later this year."

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 an engineered strain of the probiotic bacteria E. coli Nissle which consumes methionine within the gastrointestinal tract, preventing methionine absorption and conversion to homocysteine in plasma. It is the first drug candidate developed through a research collaboration between Synlogic and Ginkgo Bioworks and the first investigational medicine developed on Ginkgo's platform to enter the clinic. In 2021, Synlogic shared preclinical data for SYNB1353 that demonstrated the lowering of blood homocysteine levels in non-human primates and mouse models. Synlogic expects to share results from the Phase 1 study of SYNB1353 in healthy volunteers by the end of 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 first half of 2023, 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 reproducible, target-specific drug design. Synlogic uses programmable, precision genetic engineering of well-characterized probiotics to exert localized activity for therapeutic benefit, with a focus on metabolic and immunologic diseases. In addition to its clinical programs, Synlogic has a research collaboration with Roche on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease. Synlogic has also developed two drug candidates through a research collaboration with Ginkgo Bioworks: SYNB1353, designed to consume methionine for the potential treatment of HCU, and SYNB2081, designed to lower uric acid for the potential treatment of gout. For additional information visit www.synlogictx.com.

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 safety, efficacy, and tolerability. Synlogic holds worldwide development and commercialization rights to SYNB1353 and is expected to report Phase 1 data in healthy volunteers in H2 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," "look forward," "estimate," "expect," "intend," on track," "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, including SYNB2081; 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 statements 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 U.S 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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