Synlogic Receives Positive Opinion on Orphan Designation from the European Medicines Agency for SYNB1618 for the Treatment of Phenylketonuria

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CAMBRIDGE, Mass., May 24, 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 European Medicines Agency (EMA) issued a positive opinion on the Company's application for orphan designation for SYNB1618 for the treatment of phenylketonuria (PKU). Previously, the U.S. Food and Drug Administration (FDA) granted SYNB1618 both Orphan Drug Designation and Fast Track designation.

"We are pleased that the EMA has issued a positive opinion for orphan designation for SYNB1618, in recognition of the urgent need for additional treatment options for PKU," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "This designation reflects our constructive engagement with multiple regulatory agencies as we progress our PKU program into late-stage development. We look forward to advancing our PKU program into a registrational trial in the first half of 2023."

About the European Medicines Agency Orphan Designation

The EMA's orphan designation is available to companies developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the European Union (EU). Medicines that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase and access to centralized marketing authorization.

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 research collaborations with Roche on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease and with Ginkgo Bioworks on additional undisclosed preclinical assets. For additional information visit www.synlogictx.com.

About SYNB1618 and SYNB1934

SYNB1618 and SYNB1934 are orally administered, non-systemically absorbed drug candidates being studied as potential biotherapeutics for phenylketonuria (PKU), an inherited metabolic disease marked by an inability to break down the amino acid phenylalanine (Phe), which can be neurotoxic. Treatment options for PKU are currently limited, with a majority of individuals with PKU in need of treatment or not adequately responding to treatment. Synlogic designed its drug candidates to reduce levels of Phe in people with PKU by consuming Phe in the gastrointestinal (GI) tract, using genetic engineering of the well-characterized probiotic *E. coli* Nissle. Findings to date support the potential for an oral, efficacious, safe, convenient, and flexible treatment option for PKU. SYNB1618 has received both Orphan Drug and Fast Track designations by the US Food and Drug Administration (FDA) and a positive opinion on Orphan Designation from the European Medicines Agency (EMA).

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," "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 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 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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