Synlogic Receives Orphan Drug Designation from FDA for SYNB1934 for Treatment of Phenylketonuria

May 9, 2023

CAMBRIDGE, Mass., May 09, 2023 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), the leading company advancing therapeutics based on synthetic biology, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to SYNB1934 for the treatment of phenylketonuria (PKU).

“We are very pleased that SYNB1934 has been granted another regulatory designation, further validating the need for new treatment options for those living with PKU,” said Aoife Brennan M.B. Ch.B., Synlogic President and Chief Executive Officer. “This designation also comes at a pivotal time as we prepare to initiate our Phase 3 trial for PKU – Synpheny-3— in the first half of this year.”

ODD is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, which generally affects less than 200,000 individuals in the U.S. ODD granted therapies entitle companies to development incentives including tax credits for qualified clinical trials, user fee exemptions, and the potential for seven years of market exclusivity after approval.

SYNB1934 has also received Rare Pediatric Disease Designation (RPDD) from the FDA and orphan designation from the European Medicines Agency (EMA).

About SYNB1934

SYNB1934 is an orally administered, non-systemically absorbed drug candidate being studied as potential biotherapeutic for phenylketonuria (PKU). PKU is an inherited rare metabolic disease caused by an inborn error of metabolism that impairs the breakdown of phenylalanine (Phe), an amino acid found in all protein-containing foods. 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 SYNB1934 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. SYNB1934 has been granted Rare Pediatric Disease and Orphan Drug designations by the U.S. Food and Drug Administration (FDA) and orphan designation from the European Medicines Agency (EMA).

About Synlogic

Synlogic is the leading company advancing therapeutics based on 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), enteric hyperoxaluria and gout. 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 immunological 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 (IBD). 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.

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," “prepare” 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 SYNB1934, SYNB1353, SYNB8802 and SYNB2081 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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Source: Synlogic, Inc.