Synlogic Granted Fast Track Designation from FDA for labafenogene marselecobac (SYNB1934) for Treatment of Phenylketonuria

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CAMBRIDGE, Mass., July 11, 2023 (GLOBE NEWSWIRE) -- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company advancing novel, oral, non-systemically absorbed biotherapeutics to transform the care of serious diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to labafenogene marselecobac (previously known as SYNB1934) for the treatment of phenylketonuria (PKU). Labafenogene marselecobac has also received Rare Disease Designation (RPDD) and Orphan Drug Designation (ODD) by the FDA and orphan designation from the European Medicines Agency (EMA).

“We are pleased that this potentially transformative therapy has now received three important regulatory designations from the FDA, and orphan designation from the EMA, reflecting a shared understanding of the urgent need for new medical treatment options that can effectively and safely lower Phe levels in patients with PKU,” said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. “This milestone re-enforces our own urgency as we execute our pivotal study, Synpheny-3.”

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.

About labafenogene marselecobac

Labafenogene marselecobac (previously known as SYNB1934) is an orally administered, non-systemically absorbed, potential treatment for phenylketonuria (PKU), a rare metabolic disease caused by inherited mutations that impair the breakdown of phenylalanine (Phe), an amino acid found in all protein-containing foods. The goal of PKU management is to reduce plasma Phe below neurotoxic levels, reducing risk of neurocognitive complications. Current treatment options for PKU are limited due to safety and efficacy, leaving the majority of people living with PKU without medical management and with uncontrolled Phe. Synlogic designed labafenogene marselecobac to target and consume Phe in the GI tract, by applying precision genetic engineering to a well-characterized probiotic. Results to date indicate the potential for labafenogene marselecobac as the first therapeutic for PKU approved as both a monotherapy and adjunctive medical treatment, and following successful Phase 2 results, it has advanced to Synpheny-3, a global, pivotal Phase 3 study. Labafenogene marselecobac has received Orphan Drug Designation (ODD), Fast Track designation and Rare Pediatric Disease Designation (RPDD) from the FDA in addition to orphan designation from the European Medicines Agency (EMA).

About Synlogic

Synlogic is a clinical-stage biotechnology company advancing novel, oral, non-systemically absorbed biotherapeutics to transform the care of serious diseases in need of new treatment options. The Company’s late-stage pipeline is focused on rare metabolic diseases, led by labafenogene marselecobac (SYNB1934), currently being studied as a potential treatment for phenylketonuria (PKU) in Synpheny-3, a global, pivotal Phase 3 study. Additional product candidates address diseases including homocystinuria (HCU), enteric hyperoxaluria, gout, and cystinuria. This pipeline is fueled by the Synthetic Biotic platform, which applies precision genetic engineering to well-characterized probiotics. This enables Synlogic to create GI-restricted, oral medicines designed to consume or modify disease-specific metabolites – an approach well suited for PKU and HCU, both inborn errors of metabolism, as well as other disorders in which the disease–specific metabolites transit through the GI tract, providing validated targets for these Synthetic Biotics. Research activities include a partnership with Roche focused on inflammatory bowel disease (IBD), and a collaboration with Ginkgo Bioworks in synthetic biology, which has contributed to two pipeline programs to date. For more information, please visit www.synlogictx.com or follow us on Twitter or LinkedIn.

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; 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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