Synlogic Provides Corporate Update and Outlook for 2023

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Pivotal Phase 3 for SYNB1934 in phenylketonuria (PKU) to initiate in H1 2023

Rare Pediatric Disease Designation received for SYNB1353 for homocystinuria (HCU)

Cash runway expected into H2 2024

CAMBRIDGE, Mass., Jan. 05, 2023 (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 summarized accomplishments for 2022 and outlined anticipated key milestones for 2023.

The Company is expected to begin its Phase 3 trial in PKU in the first half of this year. In addition, SYNB1353 was granted Rare Pediatric Disease Designation (RPDD) by the U.S. Food and Drug Administration (FDA) for the potential treatment of HCU. RPDD is granted to drugs which are under development for rare childhood diseases. RPDD means that the sponsor may be entitled to receive a pediatric priority review voucher (pPRV) if the drug is initially approved for that rare childhood disease.

“With three positive clinical readouts in three different diseases in the fourth quarter, 2022 was an extraordinary year for Synlogic in terms of advancing the potential for Synthetic Biotics to become transformative medicines,” said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. “We are delighted to continue the momentum in 2023 as we look towards initiation of Synpheny-3, the pivotal Phase 3 study for SYNB1934 in PKU, and also appreciate the recent granting of Rare Pediatric Disease Designation for SYNB1353 for HCU by the FDA.”

2022 Accomplishments

Major program and corporate milestones achieved in 2022 included the following:

- Positive Phase 2 top-line data readout for PKU program, confirming SYNB1934 to advance to Phase 3
- Proof of concept achieved with Phase 1b top-line data for SYNB8802 for enteric hyperoxaluria
- Completion of Phase 1 study for SYNB1353 for HCU, achieving proof of mechanism
- Research milestone achieved from collaboration with Roche for novel Synthetic Biotic for the treatment of inflammatory bowel disease (IBD)
- SYNB2081 named as new drug candidate for the treatment of gout
- Positive Opinion on Orphan Designation received from the European Medicines Agency for SYNB1618 for PKU
- Fast Track designation, Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) received for SYNB1353 for HCU

Anticipated 2023 Milestones

- Initiation of Phase 3 clinical trial of SYNB1934 for PKU in H1 2023
- Presentation of full data from Phase 2 PKU study
- Advancing SYNB1353 to Phase 2 study in patients with HCU
- Presentation of data from Phase 1b studies of SYNB8802, in development for enteric hyperoxaluria
- Progression of preclinical pipeline programs, including partnerships

The Company also confirms that its current cash balance is expected to take the company into H2 2024. Synlogic will also report its 4Q and full year 2022 financial results in March 2023.

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), 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 or 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" 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, 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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