synlogic

Synlogic Announces International Nonproprietary Name Selection for SYNB1934

June 28, 2023

The World Health Organization has approved "labafenogene marselecobac"

Name attributes recognize Synlogic's proprietary technology and commitment to phenylketonuria community

CAMBRIDGE, Mass., June 28, 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 International Nonproprietary Names (INN) Expert Committee of the World Health Organization (WHO-INN) has selected "*labafenogene marselecobac*" for the nonproprietary name of the company's investigational drug for phenylketonuria (PKU), previously known as SYNB1934. Naming attributes recognize Synlogic's proprietary technology and the company's deep appreciation for, and commitment to, the PKU community.

Labafenogene marselecobac is currently being evaluated in Synpheny-3, a global pivotal clinical trial designed to evaluate the efficacy and safety of the investigational drug as a treatment for PKU. For more information about the Synpheny-3 clinical trial, visit www.pkuresearchstudy.com.

"On the heels of initiating Synpheny-3, our pivotal study for people living with PKU, receiving this INN marks another milestone as we advance this potentially transformational therapeutic to the many patients living with PKU who remain in need of a new medical treatment," said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. "With this name, we recognize PKU heroes: Mary and Sheila Jones, whose experience demonstrated the life-changing effect of Phe control in PKU. Mary and Sheila are honored in the prefix of this INN, '*marselecobac*,' and it is fitting that we announce this tribute on June 28: International PKU Awareness Day. It is our privilege to share and celebrate this milestone with those living with PKU around the world."

About labafenogene marselecobac (SYNB1934)

Labafenogene marselecobac (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) 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 <u>www.synlogictx.com</u> or follow us on <u>Twitter</u> or <u>LinkedIn</u>.

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 Synlogic's clinical trials of labafenogene marselecobac (SYNB1934), SYNB1353, SYNB802 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's flings with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Synlogic's flings 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 lect to updat

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.