Synlogic Receives Fast-Track Designation for SYNB1618, a Synthetic Biotic™ medicine for the Treatment of Phenylketonuria

April 25, 2018

– Phase 1/2a clinical study of SYNB1618 evaluating safety and tolerability as well as exploratory endpoints expected to report interim data in 2018 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 25, 2018-- Synlogic (Nasdaq: SYBX), a clinical-stage company applying synthetic biology to probiotic bacteria to develop novel living medicines, announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its clinical product candidate, SYNB1618. SYNB1618 is an oral, investigational medicine designed to metabolize phenylalanine as a treatment for phenylketonuria (PKU). Synlogic has dosed the first subjects in a Phase 1/2a clinical trial of SYNB1618 to evaluate safety and tolerability, as well as exploratory endpoints in both healthy volunteers and patients with PKU, from which the company expects to report interim data in 2018.

"The FDA's decision to grant Fast Track status to our SYNB1618 program, which has already received Orphan Drug Designation, underscores the high unmet medical need among patients with PKU. This represents another step in our regulatory strategy to advance the clinical development of SYNB1618 as expeditiously as possible," said Aoife Brennan, M.B., B.Ch., Synlogic's chief medical officer. "We look forward to continuing the development of SYNB1618 which has the potential to provide an improved treatment option suitable for all PKU patients."

The FDA Fast Track program is designed to facilitate the development of important new drugs intended to treat a serious condition and to fill an unmet medical need. The designation enables early and frequent communication between the FDA and the company throughout the drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients. Through the Fast Track program, a product may be eligible for priority review at the time of a Biologic License Application (BLA) and rolling review, which allows the company to submit completed sections of its application for review by the FDA, rather than waiting until the entire application is completed and submitted.

About SYNB1618

SYNB1618 is a Synthetic Biotic medicine in development for the treatment of Phenylketonuria (PKU), an inborn error of metabolism that results in a potentially toxic accumulation of the amino acid Phenylalanine (Phe). SYNB1618 is engineered to execute a programmed metabolic pathway designed to consume Phe and convert it into harmless metabolites, including trans-cinnamic acid in the blood which can be further metabolized in the liver and excreted as hippurate in the urine, providing potentially important biomarkers of SYNB1618's activity. SYNB1618 has demonstrated robust activity in mouse models of PKU and dose-dependent activity in healthy non-human primates. Synlogic has dosed the first subjects in a Phase 1/2a single and multiple dose-escalation, randomized, double-blind, placebo-controlled study of orally administered SYNB1618 in healthy adult volunteers and adult subjects with PKU, designed to evaluate safety, tolerability, kinetics, and pharmacodynamics as well as exploratory end-points associated with the ability of SYNB1618 to metabolize Phe. Synlogic expects to report interim data from the single ascending dose (SAD) portion of this trial in 2018 and the full data in 2019. More information on this study will be posted on https://clinicaltrials.gov.

About Phenylketonuria (PKU)

PKU is an inborn error of metabolism caused by a defect in the gene encoding phenylalanine hydroxylase (PAH), a liver enzyme that metabolizes Phe. Phe is an essential amino acid that enters the body as a component of dietary protein and can be toxic if it accumulates in the blood and brain. Current disease management of PKU involves strict dietary protein restriction with the consumption of Phe-free protein supplements. The only currently approved medication, Kuvan®, is indicated for a subgroup of patients and does not eliminate the need for ongoing dietary management. Life-long Phe control is challenging due to the highly restrictive nature of the diet and patients typically experience worsening neurological function depending on the severity of their genetic mutation and their treatment compliance. PKU is diagnosed at birth, and the National PKU Alliance estimates that there are currently 16,500 people living with the disorder in the U.S.

About Synlogic

Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotic medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The company's two lead programs, SYNB1020 and SYNB1618, target hyperammonemia as a result of liver damage or genetic disease, and PKU, respectively. When delivered orally, Synthetic Biotic medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect, with the potential to significantly improve symptoms of disease for affected patients. In addition, the company is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including liver disease, inflammatory and immune disorders, and cancer. Synlogic is collaborating with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please 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, 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,” “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 platform to develop therapeutics to address a wide range of diseases, including PKU, urea cycle disorders and other inborn errors of metabolism, hyperammonemia and other liver disorders, cancer, and inflammatory and immune disorders; the ability of SYNB1618 to lower blood phenylalanine in patients; the progress of clinical trials and the timing of data availability; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic’s technology to treat phenylketonuria and urea cycle disorders; and the advancement of our collaborations. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including: the uncertainties inherent in the 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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