Synlogic Presents Preclinical Data from Synthetic BioticTM Medicine, SYNB1618, for the Treatment of Phenylketonuria

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– SYNB1618 currently being evaluated in a Phase 1/2a clinical trial in healthy volunteers and patients with Phenylketonuria (PKU); interim data expected in 2H 2018 –

– Data presented in plenary session at ASM Microbe 2018 demonstrate lowering of blood phenylalanine (Phe) levels in an animal model of PKU and non-human primates (NHPs) –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 11, 2018-- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage drug discovery and development company applying synthetic biology to probiotics to develop novel living medicines, today announced the presentation of preclinical data from SYNB1618, an investigational Synthetic Biotic medicine currently being evaluated in an ongoing Phase 1/2a clinical trial in healthy volunteers and patients with PKU. The data demonstrate that oral administration of SYNB1618 resulted in lower blood Phe levels and a quantitative, dose-dependent production of biomarkers indicating SYNB1618-related activity in an animal model of PKU and healthy NHPs. The presentation was featured in a plenary session at the annual meeting of the American Society for Microbiology (ASM Microbe 2018), which is being held from June 7-11 in Atlanta, GA.

“For patients with PKU, life-long disease management can be challenging due to the protein-restricted diet required to accompany currently available treatments. We are encouraged by the preclinical data presented at ASM Microbe, which support the development of orally administered SYNB1618 as a potentially broadly applicable therapeutic option for patients,” said Aoife Brennan, M.B., B.Ch., Synlogic’s interim president and chief executive officer and chief medical officer. “We are currently exploring production of these same biomarkers in an ongoing Phase 1/2a clinical trial in healthy volunteers and patients with PKU, and look forward to reporting interim safety data from the dose-escalation portion of this trial in the second half of 2018.”

Synlogic’s Synthetic Biotic medicines for the treatment of inborn errors of metabolism, such as PKU, are designed to function in the gastrointestinal (GI) tract to convert metabolites that can build up to toxic levels in the blood into harmless metabolites that can be excreted from the body. SYNB1618 is a strain of a probiotic bacterium, *E.coli* Nissle, that has been engineered to metabolize Phe, an essential amino acid that at high blood levels can lead to cognitive damage, into harmless compounds, including trans-cinnamic acid (TCA). TCA can be further metabolized in the liver and excreted as hippurate in the urine, suggesting TCA and hippurate are potentially quantitative biomarkers of SYNB1618 activity.

In a Plenary Session at ASM Microbe, “Precision Microbiology,” Synlogic scientist, Vincent Isabella, Ph.D., presented data, demonstrating that:

- Phe is abundant in the small intestine and is derived from two sources, the diet and the blood. Phe in the blood re-enters the GI tract in the form of enzymes and secretions via a process known as enterorecirculation; and
- In a mouse model of PKU and in healthy NHPs, orally administered SYNB1618 can result in significant decreases in blood Phe levels and dose-responsive pharmacokinetics, as determined by dose-dependent production of biomarkers, such as plasma TCA and urinary hippurate.

More information about Synlogic’s Phase1/2a clinical trial in healthy adult volunteers and patients with PKU, can be found at https://clinicaltrials.gov under the study ID NCT03516487.

About Phenylketonuria (PKU)
PKU is 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. 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: cancer, inborn errors of metabolism, liver disease, and inflammatory and immune disorders; 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 cancer, hyperammonemia, and phenylketonuria. 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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