



## Synlogic Presents Data Demonstrating Activity of a Solid Oral Formulation of SYN1618 at American College of Medical Genetics (ACMG) Annual Meeting

April 13, 2021

- SYN1618 demonstrates proof of mechanism and phenylalanine (Phe) consumption in GI tract of healthy volunteers -  
- SYN1618 Phase 2 study in patients with PKU ongoing -

CAMBRIDGE, Mass., April 13, 2021 Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today presented data from the Phase 1 study of SYN1618 for the treatment of Phenylketonuria (PKU) during the American College of Medical Genetics (ACMG) annual meeting, being held virtually April 13-16, 2021.

The poster presentation, "[Randomized, Placebo-Controlled Study of Lyophilized Formulation of SYN1618 in Healthy Adult Volunteers](#)," was delivered by Dr. Marja Puurunen, Synlogic's Senior Medical Director. The presentation recording will be available throughout the duration of the conference.

PKU is an inherited metabolic disease that manifests at birth and is marked by an inability to break down phenylalanine, an amino acid that is commonly found in many foods. Left untreated, PKU can lead to serious neurological and neuropsychological problems.

SYN1618 is an oral investigational Synthetic Biotic medicine designed to break down phenylalanine in the GI tract as a potential treatment for patients with PKU. A solid oral lyophilized powder formulation was evaluated in a Phase 1 study in healthy volunteers. In this study, the safety, tolerability and pharmacodynamics of multiple doses of SYN1618 were assessed. Findings reported today include:

- The solid oral formulation of SYN1618 was well tolerated and metabolically active in the human GI tract.
- SYN1618 reduced the increase of plasma D5-Phe following an oral dose of the tracer in a dose-dependent manner in healthy volunteers.
- SYN1618 demonstrated evidence of activity in the fasted state i.e. without protein intake, suggesting an ability to metabolize non-dietary Phe in the GI tract.

These data support the further clinical development of this therapy for the treatment of PKU. SYN1618 continues to advance in a proof of concept Phase 2 clinical trial in adults with PKU, SynPheny, with data expected in the second half of 2021.

Learn more about Synlogic's programs and pipeline by visiting <https://www.synlogictx.com/>.

### About PKU

Phenylketonuria (PKU) is an inherited metabolic disease that manifests at birth and is marked by an inability to break down phenylalanine (Phe), an amino acid that is commonly found in many foods. Left untreated, high levels of Phe become toxic and can lead to serious neurological and neuropsychological problems affecting the way a person thinks, feels, and acts. Due to the seriousness of these symptoms, infants are screened at birth in many countries to ensure early diagnosis and treatment to avoid intellectual disability and other complications.

### About SYN1618

SYN1618 is an investigational oral drug for the treatment of Phenylketonuria (PKU) composed of an engineered Synthetic Biotic designed to lower plasma phenylalanine (Phe) levels by consuming Phe in the GI tract. A solid oral lyophilized formulation of SYN1618 was found to be safe and well-tolerated, and consumes Phe in the GI tract of healthy volunteers. Synlogic has initiated a Phase 2 study in PKU patients ([NCT04534842](#)).


### About Synlogic

Synlogic™ is bringing the transformative potential of synthetic biology to medicine. With a premiere synthetic biology platform that leverages a reproducible, modular approach to microbial engineering, Synlogic designs Synthetic Biotic medicines that target validated underlying biology to treat disease in new ways. Synlogic's proprietary pipeline includes Synthetic Biotics for the treatment of metabolic disorders including Phenylketonuria (PKU) and Enteric Hyperoxaluria. The company is also building a portfolio of partner-able assets in immunology and oncology.

### 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," "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, and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; and the expected timing of Synlogic's clinical trials of SYN1618 and availability of clinical trial data including Phase 2 data of SYN1618 for the treatment of PKU. 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 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 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.

 View original content: <http://www.prnewswire.com/news-releases/synlogic-presents-data-demonstrating-activity-of-a-solid-oral-formulation-of-synb1618-at-american-college-of-medical-genetics-acmg-annual-meeting-301267768.html>

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