



## Synlogic Progresses Clinical and Preclinical Pipeline and Outlines 2018 Catalysts

January 5, 2018

- Presentation of full clinical data from first in-human study of Synthetic Biotic™ medicine expected in 1Q 2018–
- IND for SYN1020 for the treatment of hyperammonemia in patients with liver disease has been cleared by the FDA–
- Additional trials in patients with UCD and PKU expected to begin in 2018 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 5, 2018-- Synlogic ([Nasdaq: SYBX](#)), a clinical-stage company applying synthetic biology to probiotics to develop novel living medicines, today provided an overview of recent progress and outlined key objectives and anticipated milestones for 2018.

"For Synlogic, 2017 was a landmark year in which we made significant clinical progress with the completion of the first-in-human trial of our Synthetic Biotic platform," said J.C. Gutiérrez-Ramos, Ph.D., Synlogic's president and chief executive officer. "Importantly, this study in healthy volunteers provided the first ever demonstration of a dose-dependent effect on a systemic metabolite by an orally-administered living medicine which functions in the gut. We demonstrated that our Synthetic Biotic medicine was safe and well tolerated, and gained valuable experience in manufacturing, dosing and clinical evaluation of this new therapeutic modality. In 2018 we expect to present the full data from this study and further validate the platform with several clinical catalysts including the initiation of three clinical trials in our two lead programs for hyperammonemia and phenylketonuria."

### 2018 Goals and Catalysts:

*SYNB1020: An orally delivered, first-in-class, Synthetic Biotic medicine designed for treatment of elevated blood ammonia levels (hyperammonemia) in genetic urea cycle disorders (UCDs) or in chronic liver disease.*

- Plan to present full data from Synlogic's first-in-human clinical study evaluating SYN1020 in healthy volunteers at two medical meetings in the first quarter of 2018:
  - Society for Inherited Metabolic Disorders (SIMD) Annual Meeting – March 11-14, 2018, in San Diego, CA.
  - International Conference on Ureagenesis Defects: Novel Models and Treatment Options – March 19-21, 2018, in Engadin, Switzerland.
- Initiation of Phase 1b/2a study in cirrhotic patients with elevated ammonia in the first quarter of 2018, with interim data expected by year-end. An Investigational New Drug (IND) application has been cleared by the U.S. Food and Drug Administration (FDA) enabling Synlogic to initiate this clinical trial.
- Initiation of second Phase 1b/2a study in UCD patients in mid-2018, with data expected in 2019.

*SYNB1618: An orally delivered, Synthetic Biotic medicine designed for the treatment of phenylketonuria (PKU)*

- Initiation of Phase 1 SAD/MAD study in healthy volunteers and PKU patients in the first half of 2018, with interim data expected in the second half of 2018.

### *Pre-clinical data and early pipeline programs*

- Additional data to be presented at major scientific and medical meetings throughout the year demonstrating the breadth of Synlogic's Synthetic Biotic platform in new indications, including data from the company's research and preclinical immunology program.

### *Corporate*

- Advancement of collaborations with AbbVie in inflammatory bowel disease (IBD) and Ginkgo in neurological and liver disease.
- Continued exploration of additional strategic opportunities to expand the platform's reach.

### 2017 Accomplishments and Highlights:

*SYNB1020:*

- Granted Fast Track Designation from the FDA in UCDs.
- Completed Phase 1 trial and reported top-line data from healthy volunteers. The study demonstrated safety and tolerability at doses up to  $1.5 \times 10^{12}$  CFU daily, as well as proof-of-mechanism with a statistically significant, dose-dependent effect on plasma nitrate in stable isotope tracer studies using  $^{15}\text{NH}_4\text{Cl}$ . These data suggest that, functioning from the gut, SYN1020 could potentially have a clinically meaningful effect in patients with elevated blood ammonia levels.

SYNB1618:

- Granted Orphan Drug Designation from FDA for treatment of PKU.
- Presented positive pre-clinical data at the International Congress of Inborn Errors of Metabolism (ICIEM) in support of further development of SYN1618 for the treatment of PKU, and SYN-MSUD for the treatment of Maple Syrup Urine Disease (MSUD).

#### Corporate

- Closed merger with Mirna Therapeutics and successfully listed on Nasdaq exchange under ticker symbol SYBX.
- Achieved first milestone in AbbVie collaboration to develop Synthetic Biotic-based treatments for IBD.
- Announced a strategic collaboration with Ginkgo Bioworks to discover new living medicines to treat neurological and liver disorders.
- Grew organization to support increased clinical activity and expansion of development and manufacturing capabilities, including key hires in corporate development, human resources and legal departments which will support continued evolution of the company as it advances its platform of Synthetic Biotic medicines.

#### About Synthetic Biotic Medicines

Synlogic's innovative new class of Synthetic Biotic medicines 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 target a group of rare metabolic diseases – inborn errors of metabolism (IEM). Patients with these diseases are born with a faulty gene, inhibiting the body's ability to break down commonly occurring by-products of digestion that then accumulate to toxic levels and cause serious health consequences. When delivered orally, these medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect. Synthetic Biotic medicines are designed to clear toxic metabolites associated with specific metabolic diseases and have the potential to significantly improve symptoms of disease for affected patients.

#### 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's initial pipeline includes Synthetic Biotic medicines for the treatment of rare genetic diseases, such as urea cycle disorders (UCD) and phenylketonuria (PKU). 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](http://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: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; 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 hyperammonemia and phenylketonuria; the expected timing of Synlogic's anticipated clinical trial initiations; the advancement of our collaborations, and the benefit of orphan drug status. 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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