Synlogic Progresses Clinical and Preclinical Pipeline and Outlines 2019 Catalysts

January 3, 2019

– Presentation of topline clinical data from studies of Synthetic Biotic™ medicines, SYNB1020 and SYNB1618, in patients expected mid-2019 –

– Investigational New Drug (IND) application for SYNB1891, Synlogic's first immuno-oncology program, expected in 2H2019 –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 3, 2019-- Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage drug discovery and development company applying synthetic biology to beneficial microbes to develop novel living medicines, today provided an overview of recent progress and outlined key objectives and anticipated milestones for 2019.

"2018 was a significant year for Synlogic as we advanced our two lead clinical programs and platform. We have demonstrated proof of mechanism in both programs in healthy volunteers and are currently evaluating safety and activity in patients with disease. In addition, we broadened our pipeline with the addition of our first immuno-oncology development candidate, SYNB1891," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "In 2019 we look forward to presenting data from our two ongoing clinical programs that will inform the development of our Synthetic Biotic platform. With the recent expansion of our internal GMP-manufacturing capabilities, we are well positioned to maintain the momentum of the past year and continue to advance programs through clinical development as expeditiously as possible."

2019 Goals and Catalysts

Pipeline

- ***SYNB1020:*** An orally delivered, first-in-class, Synthetic Biotic medicine designed for treatment of elevated blood ammonia levels (hyperammonemia) in chronic liver disease or genetic urea cycle disorders (UCDs).
    - In mid-2019, Synlogic expects to present top-line data from its randomized, double-blind, placebo -controlled Phase 1b/2a clinical trial evaluating SYNB1020 in patients with cirrhosis and elevated ammonia. The main endpoints of the study are safety and tolerability, as well as evidence of ammonia lowering in patients.
- ***SYNB1618:*** An orally delivered, Synthetic Biotic medicine designed for the treatment of phenylketonuria (PKU).
    - In mid-2019, Synlogic expects to present top-line data from its randomized, double-blind, placebo-controlled Phase 1/2a clinical trial evaluating SYNB1618 in patients with PKU. The study is designed to evaluate safety and tolerability in this population as well as pharmacokinetics and pharmacodynamics as determined by the production of biomarkers specifically associated with SYNB1618 activity.
- ***SYNB1891:*** Synlogic's first immuno-oncology (IO) development candidate, a STING agonist-producing Synthetic Biotic medicine, designed to act as a dual innate immune activator, for the treatment of non-immunologically responsive solid tumors.
    - In the second half of 2019 the Company expects to file an IND application to enable advancement of SYNB1891 into a Phase 1 clinical study.

- ***Pre-clinical data and early pipeline programs:***
    - The company expects to publish and present data at major scientific and medical meetings throughout the year demonstrating the breadth and potential of its Synthetic Biotic platform.
    - Synlogic and AbbVie will continue to advance their ongoing collaboration to develop a Synthetic Biotic medicine for the treatment of inflammatory bowel disease (IBD).

Corporate

- Synlogic ended the third quarter of 2018 with $133 million in cash and cash equivalents and expects that this will fund Company operations through 2020 under its current plan.
- The Company will continue to explore additional strategic opportunities to expand the reach of its Synthetic Biotic platform.

2018 Accomplishments and Highlights:

Pipeline

- ***SYNB1020:***
    - Dosed first patient in Phase 1b/2a trial of SYNB1020 for the treatment of hyperammonemia in patients with

cirrhosis and elevated ammonia. The clinical trial is a single and multiple dose-escalation, randomized, double-blind, placebo-controlled study of orally administered SYNB1020 in patients with cirrhosis and elevated blood ammonia, designed to evaluate safety, tolerability, kinetics, and pharmacodynamics as well as the ability of SYNB1020 to lower blood ammonia. Synlogic enrolled and treated an initial open-label sentinel cohort of six subjects with mild disease to ensure that SYNB1020 was safe in patients with liver disease who often have compromised barrier function and might be susceptible to infection. This part of the study is complete and Synlogic is enrolling patients with more advanced disease with elevated blood ammonia at baseline.
    - Presented data supporting continued development of SYNB1020 for the treatment of liver disease at the annual meeting of the American Association for the Study of Liver Diseases (AASLD). Synlogic presented data from a cross-sectional study designed to establish ammonia measurement parameters and ammonia levels in healthy volunteers at clinical sites that are participating in Synlogic's ongoing Phase 1b/2a clinical trial of SYNB1020 in patients with cirrhosis and elevated ammonia. Preclinical data from a rat model were also presented by Synlogic's collaborators that demonstrated dose-dependent lowering of blood ammonia by Synthetic Biotic strains designed to consume ammonia, confirming earlier preclinical observations in mouse models of liver disease.
- ***SYNB1618:***
    - Announced positive interim data from the healthy volunteer arm of its ongoing Phase 1/2a clinical trial evaluating SYNB1618 for the treatment of PKU. The data demonstrated a statistically significant, dose-dependent effect on treatment-associated biomarkers, indicating proof-of-mechanism, and also established a go-forward dose for the treatment arm in patients with PKU.
    - Published preclinical data in *Nature Biotechnology* identifying key biomarkers of SYNB1618 activity in healthy animal and disease models. The data demonstrated that oral administration of SYNB1618 significantly reduced blood phenylalanine (Phe) levels, the key metabolite associated with PKU, in mouse models of PKU and resulted in dose-dependent pharmacodynamics in healthy non-human primates (NHPs).
    - Fast Track designation granted to SYNB1618 for PKU by the U.S. Food and Drug Administration (FDA).
- ***SYNB1891:***
    - Presented preclinical data highlighting the potential of Synthetic Biotic medicines in IO and announced first IO clinical candidate at the annual meeting of the Society for Immunotherapy of Cancer (SITC). A webcast of the presentation is available on the Synlogic website. Data presented at the meeting demonstrate the platform's potential for the treatment of cancer and inflammation and specifically highlight the unique advantages of Synlogic's approach to stimulate the innate immune system.

Corporate

- Successfully completed two public offerings of common stock in January and April, resulting in approximately $83 million in total net proceeds.
- The Company announced executive leadership changes including the appointment of Aoife Brennan, M.B., B.Ch., as president and chief executive officer, and the appointment of Antoine Awad as Head of Technical Operations.
- Synlogic expanded its manufacturing capabilities to enable production of clinical trial material for its oral and immuno-oncology programs via entry into an agreement to lease GMP clean-room space from the Azzur Group, LLC. The agreement provides the Company with infrastructure that enables advancement of clinical programs through early and mid-phase studies and supports the production of both solid and oral formulations.
- Advanced collaboration with AbbVie to develop Synthetic Biotic-based treatments for IBD resulting in payment to Synlogic of a $2.0 million milestone.
- Synlogic was added to both the Russell 3000®Index and the NASDAQ Biotechnology Index® (Nasdaq: NBI).

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 beneficial microbes to perform or deliver critical functions missing or damaged due to disease. Synthetic Biotic medicines are designed to act locally and have a systemic effect to address disease in patients. Synlogic's two lead programs, SYNB1020 and SYNB1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYNB1891 as an intratumorally administered Synthetic Biotic medicine for the treatment of cancer. In addition, the company is leveraging the broad potential of its platform to create additional Synthetic Biotic medicines for the treatment of liver disease, as well as inflammatory and immune disorders including Synlogic's collaboration 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190103005225/en/

Source: Synlogic, Inc.

MEDIA CONTACT:
Courtney Heath
Phone: 617-872-2462
Email: courtney@scientpr.com

INVESTOR CONTACT:
Elizabeth Wolffe, Ph.D.
Phone: 617-207-5509
Email: liz@synlogictx.com