Synlogic Outlines Upcoming Clinical Milestones

January 11, 2021

- Clinical proof of concept data in 2021 anticipated across multiple programs -

CAMBRIDGE, Mass., Jan. 11, 2021 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today outlined significant clinical milestones for 2021 and provided an overview of recent progress.

"With three programs in clinical trials, multiple proof of concept opportunities, and a preclinical portfolio advancing rapidly towards the clinic, Synlogic is poised for success with a number of data readouts coming in 2021," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "2020 was a year we will not forget. Despite the external challenges, the Synlogic team moved our programs forward with grit and resilience. We enter 2021 with momentum and the opportunity to truly see the potential of novel Synthetic Biotic medicines to make a meaningful difference in patients' lives."

Synlogic anticipates clinical proof of concept data in 2021 across two metabolic programs, SYNB1618 for the treatment of Phenylketonuria (PKU) and SYNB8802 for the treatment of Enteric Hyperoxaluria, as well as continued advancement of SYNB1891 for the treatment of solid tumors and lymphomas.

Execution Across Clinical Pipeline: Metabolic Programs

- **Progression of a proof of concept Phase 2 clinical trial of SYNB1618 for the treatment of Phenylketonuria (PKU)**
  - SYNB1618 is an investigational drug composed of a Synthetic Biotic medicine designed to consume phenylalanine (Phe) in the gastrointestinal (GI) tract for the treatment of PKU in patients regardless of age or disease type.
  - A solid oral formulation of SYNB1618 has been shown to metabolize Phe in the GI tract in a healthy volunteer study.
  - The SynPheny-1 study evaluates plasma Phe lowering of SYNB1618 in adult PKU patients who do not benefit from, or do not tolerate, existing therapies such as Kuvan or Palynziq.
  - Synlogic anticipates data from SynPheny-1 will be available mid- 2021.

- **Progression of a Phase 1 clinical study of SYNB8802 for the treatment of Enteric Hyperoxaluria**
  - SYNB8802 is an investigational drug composed of a Synthetic Biotic medicine designed to consume oxalate in the GI tract and lower urinary oxalate levels, potentially reducing kidney damage due to Enteric Hyperoxaluria.
  - In data presented at the American Society of Nephrology's (ASN) 2020 Kidney Week, SYNB8802 was shown to reduce urinary oxalate in two animal models of Hyperoxaluria.
  - The Phase 1 clinical study evaluates the safety, tolerability, and potential for urinary oxalate lowering in healthy volunteers and patients.
  - The study has two parts: Part A is a multiple ascending dose study in healthy volunteers; Part B is a placebo controlled, cross-over design study in patients with Enteric Hyperoxaluria following Roux-n-Y gastric bypass surgery which provides an opportunity to demonstrate proof of concept.
  - Synlogic anticipates data from Part B of the study will be available mid-2021.

Execution Across Clinical Pipeline: Immunomodulation Programs

- **Advancement of SYNB1891 into combination arm dosing with PDL1 checkpoint inhibitor in ongoing Phase 1 study**
  - SYNB1891 is an investigational drug composed of an intratumorally delivered Synthetic Biotic medicine designed to produce a STING agonist and act as a dual innate immune activator for the treatment of advanced solid tumors and lymphoma.
  - SYNB1891 is currently being evaluated in a Phase 1 study that has two parts:
    - Part A is a monotherapy arm that has enrolled four dose cohorts to date.
      - A maximum tolerated dose has not been reached and dose escalation continues.
    - Part A of the study has demonstrated target engagement and activation of the STING pathway.
    - Part B of the study will combine escalating dose levels of SYNB1891 with a fixed dose of the PD-L1 checkpoint inhibitor atezolizumab, to establish a recommended Phase 2 dose for the combination regimen.
  - Synlogic anticipates additional data from cohorts in both arms will be available in mid to late 2021.

Preclinical Roadmap

- Synlogic continues to advance preclinical programs including additional effectors for immune-oncology; immune regulation targets for treatment of inflammatory bowel disease and other inflammatory disorders; and additional undisclosed rare metabolic diseases.
- Further updates on these programs will be shared as they advance towards the clinic.

2020 Corporate Milestones

- Synlogic strengthened leadership with the following appointments:
  - Synlogic appointed Dr. David Hava, Ph.D., as Chief Scientific Officer. Dr. Hava brings over a decade of senior experience in research and development to Synlogic, including deep academic expertise in pillars of synthetic biology.
  - Synlogic promoted Antoine 'Tony' Awad to Chief Operating Officer. Mr. Awad brings over 15 years of experience in the biotechnology and pharmaceutical industry with substantial experience in the development and manufacturing of novel therapeutics from pre-IND studies through global commercialization.
  - Synlogic appointed Michael Heffernan, seasoned entrepreneur and biopharmaceutical leader, and Dr. Michael Burgess, physician scientist and expert in translational development, to its board of directors.
- Synlogic and Ginkgo Bioworks advanced their long-term strategic platform collaboration that provides expanded synthetic biology capabilities to Synlogic.
  - Ginkgo and Synlogic are collaborating on multiple efforts including metabolic and immunomodulation programs, and assessment of the potential application of Synthetic Biotics for vaccine development.
- Synlogic ended the third quarter of 2020 with $102.0 million in cash, cash equivalents and short- and long-term investments and expects this will fund company operations through 2022 under its current plan.

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

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 (HOX). 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; 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 including the Phase 1 study for SYNB1891 and SYNB8802 and the Phase 2 study of SYNB1618, and availability of clinical trial data from that study and other studies.

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.

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