Synlogic Provides Summary of Impact of COVID-19 on Clinical Program Progress and Operational Activities

March 30, 2020

CAMBRIDGE, Mass., March 30, 2020 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines called Synthetic Biotic ™medicines, today provided an update on its business operations and expected clinical activities as a result of the COVID-19 pandemic. In the interest of patient safety, as well as aligning with the needs of clinical sites, Synlogic expects that enrollment of subjects into its planned Phase 2 clinical study of SYNB1618 in patients with phenylketonuria (PKU) will be delayed and expects slower enrollment of new subjects into its ongoing Phase 1 clinical trial of SYNB1891.

"The COVID-19 pandemic has generated global challenges and we have all had to assess and redefine our priorities," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "Like others in our industry we have moved quickly to respond; prioritizing the safety of patients and our employees, alleviating the burden on our clinical trial sites, while continuing to execute on our business strategy and work within institutional and government guidelines."

"We remain committed to advancing our Synthetic Biotic medicines and developing novel therapeutics to meet significant unmet patient needs in a range of indications from rare metabolic diseases to cancer," continued Brennan. "I am extremely proud of the Synlogic team who have exemplified this commitment through their resilience and dedication to our mission as we adjust to this unprecedented situation."

"There is still a great deal of uncertainty as to the duration and ultimate impact of this pandemic on the healthcare system and we continue to evaluate the situation as it evolves," stated Richard Riese, M.D., Ph.D., Synlogic's chief medical officer. "We will continue to execute on our overall development plans while adjusting to our new reality. We believe our updated plans will not only protect the health and safety of the patients that we serve in these trials but aid our clinical sites as they navigate tremendous operational and caregiving challenges in response to the pandemic."

Updates to Pipeline Programs

- ***SYNB1618:*** SYNB1618 is an orally delivered, Synthetic Biotic medicine designed to consume phenylalanine (Phe) in the gastrointestinal tract for the treatment of PKU in patients regardless of age or disease type.
    - While Synlogic intends to continue to work with sites to complete preparatory work, it does not expect to be able to enroll subjects into its Phase 2 clinical trial of SYNB1618 until it is safe for patients to enter clinical trial sites. The trial is designed to evaluate safety and tolerability of a solid formulation of SYNB1618 as well as its potential to lower blood Phe levels in PKU patients.
- ***SYNB1891:*** Synlogic's first clinical immuno-oncology (IO) program, SYNB1891, is an intra-tumorally delivered Synthetic Biotic medicine designed to produce a STING agonist and act as a dual innate immune activator for the treatment of refractory solid tumors and lymphoma.
    - SYNB1891 is being evaluated as a monotherapy in a Phase 1 open-label, multicenter, dose escalation clinical trial (NCT04167137) in patients with advanced solid tumors or lymphoma. Four U.S. sites have been activated to enroll patients and subjects in the first two cohorts have been dosed.
    - While we anticipate the study will remain open and currently enrolled patients will continue on study, Synlogic expects enrollment of new patients to slow which has the potential to impact the availability of data in 2020.
    - After establishing a maximum tolerated dose for SYNB1891, Synlogic plans to initiate a second arm of the trial in which subjects will receive escalating dose levels of SYNB1891 in combination with a fixed dose of the checkpoint inhibitor, atezolizumab (Tecentriq®), in order to establish a recommended dose for SYNB1891 for the combination regimen.
- ***Pre-clinical data and early pipeline programs:***
    - In its enteric hyperoxaluria program, Synlogic expects to move a clinical candidate into IND-enabling studies in 2020.

Financial and Operational Update

- The safety and wellbeing of Synlogic employees is a top priority for us. As of March 16th, Synlogic transitioned all non-laboratory personnel to work from home. Business-critical laboratory and manufacturing activities are continuing under new guidelines designed to reduce the risk of transmission of SARS-CoV-2 and maximize the safety of employees. Synlogic continues to assess business-critical activities and priorities, company policies and employee support.
- Synlogic will continue to explore additional business development opportunities and collaborations to maximize the potential of its Synthetic Biotic platform, including through potential application of the platform to the development of therapeutic options for the prevention of COVID-19.
- Synlogic ended 2019 with $127.1 million in cash, cash equivalents and short- and long-term investments and reiterates

that it expects this will fund Company operations into 2022 under its current plan.

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. When delivered orally, Synthetic Biotic medicines are designed to function in 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. The Company's lead program in this area, SYNB1618, targets 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 inflammatory and immune disorders, and cancer. Synlogic's first immuno-oncology program, SYNB1891, is in clinical development for the treatment of solid tumors and lymphoma. 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, including statements regarding Synlogic's plans and expectations for the development of SYNB1618 and SYNB1891. 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 impact of COVID-19 on our product candidates clinical trials, development and business operations; the potential of Synlogic's platform to develop therapeutics to address a wide range of diseases including: cancer, metabolic 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; and the expected timing of Synlogic's clinical trials and availability of clinical trial data. 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 and clinical 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 to download multimedia:http://www.prnewswire.com/news-releases/synlogic-provides-summary-of-impact-of-covid-19-on-clinical-program-progress-and-operational-activities-301031386.html

SOURCE Synlogic, Inc.

Media Contact: Caroline Rufo, Ph.D., MacDougall, Phone: 781-235-3060, Email: crufo@macbiocom.com; Investor Contact: Elizabeth Wolffe, Ph.D., Synlogic, Inc., Phone: 617-207-5509, Email: liz@synlogictx.com