Synlogic Initiates Phase 1 Study of SYNB8802 for the Treatment of Enteric Hyperoxaluria

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CAMBRIDGE, Mass., Nov. 4, 2020 /PRNewswire/ -- Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company bringing the transformative potential of synthetic biology to medicine, today announced it has treated the first healthy volunteer in its Phase 1 study of the investigational Synthetic Biotic medicine SYNB8802 for the treatment of Enteric Hyperoxaluria (HOX).

"We are thrilled to be moving SYNB8802 into the clinic ahead of schedule," said Aoife Brennan, M.B. Ch.B., Synlogic's President and Chief Executive Officer. "Leveraging our Synthetic Biotic platform allowed us to move rapidly from candidate declaration to the initiation of the Phase 1 study in under nine months. Patients with dangerously high urinary oxalate levels today have few options, and we will move this program forward with a sense of urgency to meet their needs."

Enteric Hyperoxaluria is an acquired metabolic disorder caused by increased absorption of dietary oxalate, which is present in many healthy foods, making it almost impossible to control with diet alone. Enteric Hyperoxaluria often occurs as a result of a primary insult to the bowel, such as inflammatory bowel disease, short bowel syndrome, or as a result of surgical procedures such as Roux-en-Y bariatric weight-loss surgery. Enteric Hyperoxaluria results in dangerously high levels of urinary oxalate, which causes progressive kidney damage, kidney stone formation, and nephrocalcinosis. There are no approved treatment options.

SYNB8802 is an engineered non-pathogenic strain of E. coli (Nissle), using Synlogic's Synthetic Biotic platform, designed to consume oxalate in the GI tract and lower urinary oxalate levels, potentially reducing kidney damage due to Enteric Hyperoxaluria. SYNB8802 is administered orally.

Synlogic recently presented preclinical data on SYNB8802 at the American Society of Nephrology's (ASN) Kidney Week 2020. Key findings:

- SYNB8802 consumes oxalate and produces formate, a metabolite of oxalate, in vitro.
- In both nonhuman primate and mouse models of acute Hyperoxaluria, SYNB8802 significantly reduced oxalate levels at six hours relative to vehicle alone.
- Proprietary in-silico simulations of predicted human exposure suggest SYNB8802 has the potential to achieve between 20% and 50% urinary oxalate lowering in patients at doses that have been well tolerated in prior trials of Synthetic Biotic medicines.

"The Phase 1 clinical study will provide for a rapid proof of concept read out by focusing on both an initial healthy volunteer cohort as well as a cohort of patients with Enteric Hyperoxaluria after Roux-n-Y gastric bypass surgery," said Richard Riese, M.D., Synlogic's Chief Medical Officer. "This post-gastric bypass population provides an optimal cohort to assess the ability of SYNB8802 to lower urinary oxalate. We look forward to providing further updates as the study progresses."

The Phase 1 clinical 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. SYNB8802 will be assessed for safety and tolerability, and the potential to reduce urinary oxalate. Synlogic anticipates data from the study will be available in 2021.

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 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 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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