Synlogic Receives Fast Track Designation in U.S. for Lead Candidate, SYNB1020

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– Novel Synthetic Biotic™ medicine, SYNB1020, under development for the treatment of hyperammonemia due to urea cycle disorders –

CAMBRIDGE, Mass–(BUSINESS WIRE)–Synlogic™ has been granted Fast Track Designation from the U.S. Food and Drug Administration (FDA) for its lead product candidate, SYNB1020, as an oral, investigational medicine for the treatment of hyperammonemia in a group of rare genetic diseases called urea cycle disorders (UCDs). SYNB1020 is the first in a novel class of living, Synthetic Biotic™ medicines under development by Synlogic being evaluated in a Phase 1 healthy volunteers study to assess the safety and tolerability of SYNB1020. SYNB1020 is also under development as a potential treatment for hyperammonemia associated with hepatic encephalopathy (HE) due to cirrhosis.

“The FDA’s decision to grant Fast Track status underscores the high unmet medical need in UCD patients, who experience intermittent periods of hyperammonemia, resulting in serious and potentially fatal consequences,” said Aoife Brennan, M.B., B.Ch., chief medical officer at Synlogic. “We will use the advantages that Fast Track status provides to advance the development of SYNB1020 which has the potential to provide an improved treatment option for UCD patients.”

“The designation of Fast Track status by the FDA is another key step in the development of our lead product, SYNB1020, which has already received Orphan Drug Designation,” said Jose Carlos Gutierrez-Ramos, Ph.D., president and chief executive officer of Synlogic. “Fast Track status provides additional momentum as we continue to execute on our clinical program for SYNB1020.”

The FDA Fast Track program is designed to facilitate the development of important new drugs intended to treat a serious condition and to fill an unmet medical need. The designation enables early and frequent communication between the FDA and the company throughout the drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients. Through the Fast Track program, a product may be eligible for priority review at the time of a Biologic License Application (BLA) or New Drug Application (NDA) and rolling review, which allows the company to submit completed sections of its application for review by the FDA, rather than waiting until the entire application is completed and submitted.

About the SYNB1020 Clinical Program:

Synlogic has initiated a Phase 1 study in healthy volunteers to assess the safety and tolerability of SYNB1020, which is the first investigational Synthetic Biotic medicine to enter the clinic. Pending the success of this first study in healthy volunteers with SYNB1020, Synlogic plans to initiate two additional clinical trials, by mid-2018, with the investigational candidate in patients symptomatic of urea cycle disorders (UCD) and hepatic encephalopathy (HE), both diseases where patients experience elevated and toxic ammonia levels. In August 2016, SYNB1020 was granted Orphan Drug Designation for the treatment of UCD.

Synthetic Biotic medicines, such as SYNB1020, are generated using the company’s proprietary technology platform, leveraging synthetic biology to genetically reprogram probiotic bacteria to perform critical functions or deliver therapeutic factors that compensate for those missing or damaged due to disease.

About Urea Cycle Disorders:

Urea Cycle Disorders (UCDs) are a group of rare, genetic diseases estimated to occur in approximately 1 in 35,000 births in the U.S. The urea cycle is an enzymatic pathway in which waste nitrogen, produced as a by-product of protein metabolism, is converted into urea by the liver and eliminated from the body through urine. Patients with UCD carry a deficiency in one of the six enzymes necessary for completion of the urea cycle, resulting in accumulation of waste nitrogen throughout the body in the form of ammonia, a substance that is highly toxic even in small amounts.

Patients with UCD have intermittent periods of hyperammonemia, the symptoms of which can range from mild (loss of appetite, vomiting, and lethargy) to a severe hyperammonemic crisis associated with long-term cognitive or behavioural impairment, toxic encephalopathy, and even death.

Dietary protein restriction is the mainstay of disease management for patients with UCD, however such a restrictive diet remains a significant challenge for patients, especially infants and children. Patients must carefully balance their protein intake to ensure the body receives adequate nutrients for growth and development, while avoiding triggering hyperammonemia.

About Synthetic Biotic™ Medicines:

Synlogic’s innovative new class of Synthetic Biotic™ medicines leverages the tools and principles of synthetic biology to genetically reengineer beneficial, 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 promise to significantly improve the quality of life for affected patients.

About Synlogic™

Synlogic™ is pioneering the development of a novel class of living Synthetic Biotic™ medicines based on its proprietary drug discovery and development platform. Synlogic’s initial pipeline includes Synthetic Biotic medicines for the treatment of rare genetic diseases, such as Urea Cycle

Disorder (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 other diseases, such as 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 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, the future clinical development of SYNB1020 and its prospects as a potential treatment for hyperammonemia and the future development of other product candidates, such as SYNB1618. 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.

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