



Synlogic Secures Patent on Proprietary Synthetic Probiotic Bacteria for the Treatment of Hyperammonemia

November 10, 2016

First Live *E. Coli* Nissle Bacterium Modified to Assimilate Ammonia Potential Treatment of Urea Cycle Disorders and Other Forms of Hyperammonemia

CAMBRIDGE, Mass.—([BUSINESS WIRE](#))—Synlogic, a privately-held biopharmaceutical company developing novel medicines based on its proprietary synthetic biology and microbiome platform, today announced the issuance of a composition-of-matter patent, U.S. Patent No. 9,487,764, which broadly covers a live engineered bacterium modified to assimilate ammonia for the potential treatment of hyperammonemia-based diseases such as urea cycle disorders (UCDs) and hepatic encephalopathy.

"The issuance of this composition-of-matter patent validates our pioneering efforts in the field of synthetic probiotics for the treatment of serious diseases and conditions," said Jose Carlos Gutierrez-Ramos, CEO of Synlogic. "Securing this patent first is a significant milestone for the company that greatly enhances the value proposition for our lead candidate SYN1020, but also provides an important precedent for other synthetic probiotics in our portfolio."

This patent covers, among other compositions, Synlogic's lead drug candidate SYN1020 that is being developed for the potential treatment of UCDs. SYN1020 is currently in preclinical development and the company plans to file an investigational new drug application (IND) with the FDA for the potential treatment of UCDs in the first quarter of 2017. The claims of the patent also cover pharmaceutical compositions of the engineered bacterium.

About Urea Cycle Disorders

UCDs are rare but serious, potentially fatal, genetic disorders caused by mutations in one or more genes encoding enzymes in the urea cycle. These genetic mutations lead to the build-up of toxic levels of ammonia in the blood that can cause significant neurological and behavioral complications. The overall frequency of congenital UCDs varies within the literature and is most conservatively estimated at 1 per 8000 births. UCD patients are prone to significant morbidity and mortality, primarily due to neurocognitive and developmental abnormalities and frequently suffer from hepatic abnormalities. Chronic management of abnormal plasma ammonia levels (hyperammonemia) in UCD patients involves long-term dietary modification with nutritional oversight to restrict protein intake, thereby minimizing the flux of nitrogen through the urea cycle and preventing acute episodes of hyperammonemic crises. Despite recent advances in the acute and chronic management of UCDs, current treatment strategies are not sufficient, and reducing the concentration of blood ammonia in patients with hyperammonemia still represents a significant medical need. A truly transformative therapy for patients with UCDs would be that of maintaining safe concentrations of blood ammonia levels to the upper limit of normal, while allowing for diets with normal or less restrictive protein intake. SYN1020 is a live probiotic bacterium that is designed to provide enhanced ability to metabolize excess ammonia in the gut by modifying the widely used probiotic *E. coli* Nissle.

About Synlogic

Synlogic is a privately-held biopharmaceutical company based in Cambridge, Massachusetts, pioneering the development of a novel class of therapeutics, called synthetic biotics, based on its proprietary synthetic biology and microbiome platform. Synlogic's two lead therapeutic programs are being developed for the potential treatment of rare inborn errors of metabolism of Urea Cycle Disorder (UCD) and Phenylketonuria (PKU). In addition to the company's proprietary pipeline focused on rare diseases, the company is leveraging the broad potential of its synthetic biotics platform for novel drug development in major disease areas through partnerships with pharmaceutical and biotechnology companies. Synlogic is collaborating with AbbVie to develop synthetic biotics-based treatment for inflammatory bowel disease (IBD). Synlogic is backed by leading life sciences investors, including Atlas Venture, New Enterprise Associates (NEA), Orbimed, Deerfield and the Bill & Melinda Gates Foundation. For more information, please visit <http://synlogictx.com/>.

Contacts

Media Contact:

Pure Communications
Susan Heins, 864-346-8336
susan@purecommunicationsinc.com

or

Investor Contact:

Pure Communications
Matt Clawson, 949-370-8500
matt@purecommunicationsinc.com