SNIPR BIOME Announces U.S Food and Drug Administration grants Fast Track Designation for SNIPR001 for Prevention of Bloodstream Infections in Hematologic Cancer Patients

Copenhagen, January 25th, 2022: SNIPR BIOME ApS, a leading CRISPR and microbiome biotechnology company, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for SNIPR001. SNIPR001 is the company's first development candidate targeting *E. coli* in patients with hematological malignancy at risk of neutropenia. This announcement comes only a few weeks after the FDA approved the Investigational New Drug (IND) Application paving the way initiating the first clinical trial in humans.

"At SNIPR BIOME, we are extremely proud to have been granted Fast Track designation by the FDA. It underlines SNIPR001's potential to be a game-changer for hematological cancer patients at increased risk of life-threatening bloodstream infections caused by E. coli" says Dr. Christian Grøndahl, Co-founder & CEO and continues "*E. coli was recently highlighted as one of the leading pathogens associated with anti-microbial-resistance and death in a systematic review published by the scientific journal The Lancet, so there is an urgent need for new medicines targeting E. coli*".

Fast Track is an FDA process designed to facilitate the development, and expedite the review, of potential therapies that seek to treat serious conditions and fill an unmet medical need. A drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process and a rolling and/or priority review of its marketing application if relevant criteria are met.

Dr. Milan Zdravkovic, Chief Medical Officer and Head of R&D at SNIPR Biome, adds: *"With the FDA's Fast Track designation, we have reached yet another milestone and we are very pleased, that the FDA shares our view on the need to target anti-microbial resistance (AMR). Now, all our attention is directed towards initiating our first clinical trial, which is expected in H1 2022".*

SNIPR001 is being developed in collaboration with the non-profit organisation CARB-X. The aim is to target *E. coli* bacteria in the gut, and thereby prevent translocation of these bacteria from the gut into the bloodstream, while leaving the commensal bacteria in the patient's microbiome unaffected.

This precision medicine approach is harnessing a novel application of SNIPR BIOME's proprietary CRISPR/Cas technology, hereby potentially transforming the way *E. coli* infections are prevented and treated, especially in the cancer ward.

Today, there are no approved therapies for prophylactic therapy in this setting.

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About SNIPR BIOME

SNIPR BIOME is a leading CRISPR and microbiome biotech company incorporated in Copenhagen, Denmark. SNIPR BIOME is engaged in the discovery and development of CRISPR/Cas-based medicines

deploying its proprietary and patent-protected CRISPR/Cas platform. The company applies its CRISPR technologies to selectively target microbial pathogens and remodel the microbiome to address important unmet medical needs. SNIPR BIOME is pioneering a novel use of CRISPR/Cas technology to selectively and precisely eradicate target bacteria, while leaving the rest of the patient's microbial community intact. SNIPR BIOME was recently awarded a grant by CARB-X of up to 10.2m USD for CRISPR-based treatment of haematological cancer patients at risk of neutropenic fever and life-threating infections (SNIPR001). In addition, SNIPR BIOME and The University of Texas MD Anderson Cancer Center has a strategic collaboration agreement to advance new CRISPR-based microbiome therapeutics to reduce immune-related adverse events (irAE) in patients being treated with combined immune checkpoint inhibitors. The company also develops proprietary technologies for *in situ* production of therapeutics in the human microbiome. SNIPR BIOME and Novo Nordisk recently entered into a research agreement on an undisclosed target to evaluate this technology for gene therapy of the microbiome i.e., *in situ* production of therapeutics in the human microbiome. SNIPR BIOME holds an extensive portfolio of granted patents protecting CRISPR modification of microbiota as an adjunct to cancer therapy, vaccine therapy and other immunotherapies. In March 2019, SNIPR BIOME closed a $50 million Series A financing by Lundbeckfonden Emerge (Copenhagen), Life Sciences Partners (Amsterdam), North-East Family Office (Copenhagen) and Wellington Partners (Munich).
For more details, please visit: www.sniprbiome.com and follow us on Twitter @sniprbiome

About CARB-X

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) is a global non-profit partnership dedicated to supporting early development antibacterial R&D to address the rising threat of drug-resistant bacteria. CARB-X is led by Boston University and funding is provided by the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the US Department of Health and Human Services; the Wellcome Trust, a global charity based in the UK working to improve health globally; Germany's Federal Ministry of Education and Research (BMBF); the UK Department of Health and Social Care's Global Antimicrobial Resistance Innovation Fund (GAMRIF) funded by the UK Government Department of Health and Social Care (DHSC); the Bill & Melinda Gates Foundation, and with in-kind support from National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH) within the US Department of Health and Human Services. CARB-X is investing up to US$480 million from 2016-2022 to support innovative therapeutics, preventatives and rapid diagnostics. CARB-X funds only projects that target drug-resistant bacteria highlighted on the CDC's Antibiotic Resistant Threats list, or the Priority Bacterial Pathogens list published by the WHO, with a priority on those pathogens deemed Serious or Urgent on the CDC list or Critical or High on the WHO list. CARB-X is headquartered at Boston University School of Law. https://carb-x.org/. Follow us on Twitter @CARB_X

Disclaimer

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