SNIPR BIOME Initiates First-in-Human Clinical Trial with SNIPR001

Copenhagen, April 20th, 2022: SNIPR BIOME ApS, a leading CRISPR and microbiome gene therapy biotechnology company, today announced dosing of the first human subjects in its phase 1 clinical trial with SNIPR001, an orally administered CRISPR-based therapeutic.

The purpose of the study is to investigate safety and tolerability of SNIPR001 in healthy volunteers and to evaluate the effect of SNIPR001 on reducing *E. coli* colonization in the gut. The study plans to enroll 36 healthy volunteers for multiple ascending dosing of SNIPR001 (NCT05277350). SNIPR001 has been granted Fast-Track designation by the FDA and is being developed in collaboration with the US non-profit organization CARB-X.

With the initiation of the First-in-Human study SNIPR BIOME becomes a clinical stage company. The experimental CRISPR therapeutic, SNIPR001, is designed to selectively target and eradicate *E. coli* in the gut, thus preventing translocation of these bacteria to the bloodstream, in a high-risk population of hematological cancer patients at risk for neutropenia. This precision approach could transform 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.

"Today, is a very special moment for SNIPR BIOME. For the first time ever, we are dosing a CRISPR-drug candidate in humans. Getting to this point is a major achievement and I am extremely proud of the whole SNIPR BIOME team, our collaborators, and advisors and especially our skilled CMC partner, Jafral, for their relentless effort in successfully bringing our first CRISPR-medicine into humans. However, this is only the beginning, and we truly believe that SNIPR001 could have the potential to help hematological cancer patients at increased risk of life-threatening bloodstream infections caused by multidrug resistant E. coli", says Dr. Christian Grøndahl, Co-founder & CEO.

Dr. Milan Zdravkovic, Chief Medical Officer and Head of R&D at SNIPR Biome, comments: *"We are excited about having brought our first asset into humans and expect top line results around year-end. We are in parallel pursuing our pipeline of CRISPR-medicines of exciting targets within oncology, immunology and cardio-metabolism, and have an ambition of selecting the next molecule from our pipeline to move into IND enabling studies also by the end of this year"*

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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 several million-dollar grant by CARB-X 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 LinkedIn & 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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