SNIPR Biome receives funding from CARB-X to support advancement of CRISPR-medicine SNIPR001 into clinical trials in haematological cancer patients

Phase 1b/2a trial will evaluate SNIPR001 for the prevention of E.coli infections in patients undergoing hematopoietic stem cell transplantation

Copenhagen, April 22 2024: SNIPR Biome ApS ("SNIPR"), the company pioneering the development of precision medicines using CRISPR technology for microbial gene therapy, announces today that it has received $5.48 million from Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") to co-fund a Phase 1b/2a clinical trial in hematological cancer patients.

The trial will evaluate SNIPR001, the first CRISPR-armed phage therapeutic that specifically targets *E. coli* in the gut, for the prevention of *E. coli* bloodstream infections in hematological cancer patients who are undergoing hematopoietic stem-cell transplantation (HSCT) and are colonized with Fluoroquinolone Resistant (FQR) *E. coli*. Fluoroquinolone is recommended in the US for prophylaxis of bacterial infections and febrile neutropenia in hematological cancer patients at high risk of neutropenia.

Despite the significant advances in hematologic cancer therapy over the past decade, infectious complications, and antimicrobial resistance (AMR) continue to pose significant threats to patients and clinical outcomes[1]. Currently, there are no approved therapies for the prevention of bloodstream infections (BSIs) in hematological cancer patients. SNIPR Biome is developing SNIPR001 to address this urgent unmet need to combat infections in hematological cancer patients.

Preclinical data published in *Nature Biotechnology* described SNIPR001's ability to selectively target and remove antibiotic-resistant *E. coli* strains in the gut, potentially offering a safe treatment which preserves the rest of the gut microbiome. This was supported by interim Phase 1 data published in 2023, which showed that oral dosing of SNIPR001 over seven days across three dosing levels in 24 healthy individuals was well tolerated. Furthermore, SNIPR001 could be recovered in faeces from treated individuals in a dose-dependent manner, and treatment with SNIPR001 numerically lowered gut *E. coli* levels.

Anticipated to begin later this year, the randomized, double-blinded Phase 1b/2a trial will investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of orally administrated SNIPR001 in 24 patients. It will be conducted at up to 10 sites across Europe and the United States.

CARB-X, a global non-profit partnership dedicated to supporting early-stage antibacterial research and development to address the rising threat of drug-resistant bacteria, has been a long-term collaborator with SNIPR in this field. The funding announced today enables SNIPR to move SNIPR001 into Phase 1b/2a clinical trials and will serve as a cornerstone for a further significant fundraise to enable the Company to continue development of its pipeline of CRISPR-based AMR and gut-directed gene therapies.

Dr Christian Grøndahl, Co-founder and CEO of SNIPR Biome, commented: *"Antibiotic resistance is one of healthcare's biggest problems today, affecting treatment efficacy and survival among patients who are often already very sick. We are using our knowledge of gene editing and synthetic biology to create highly specific, 'designer' bacteria and phage to disrupt, edit or add genes, and deliver these precision medicines in a carefully targeted way. We are pleased to be continuing our partnership with CARB-X*

[1] So M. Determining the Optimal Use of Antibiotics in Hematopoietic Stem Cell Transplant Recipients. JAMA Netw Open. 2023 Jun 1;6(6):e2317101

who share our commitment to developing therapies for vulnerable patients."

Erin Duffy PhD, Chief of Research & Development, CARB-X, said: "Having underscored safety for SNIPR001 in healthy subjects, SNIPR Biome is now focusing on demonstrating proof-of-mechanism for this novel product, with our support. We are keen to establish a link between gut decolonization and prevention of infection as a novel approach to antimicrobial resistance, and SNIPR001 offers the possibility of doing so."

CARB-X funding for this research is supported by the Biomedical Advanced Research and Development Authority under agreement number: 75A50122C00028, and by awards from Wellcome (WT224842), and Germany's Federal Ministry of Education and Research (BMBF). The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.

Ends

About SNIPR001

SNIPR001, a CRISPR-armed phage therapeutic that specifically targets *E. coli* in the gut, is designed to prevent infections from spreading into the bloodstream and represents a promising advancement against antibiotic-resistant pathogens. The pre-clinical studies of SNIPR001 published in *Nature Biotechnology*[2] demonstrated the product's activity against multi-drug resistant strains of *E. coli* and its specificity towards *E. coli* with no off-target effects toward any of the tested non-*E. coli* strains. SNIPR successfully completed a Phase 1 trial in the US, also funded by CARB-X, demonstrating safety of SNIPR001 and target engagement with *E. coli* in the gut of healthy subjects without disturbing the overall gut microbiome (NCT05277350), supporting its potential as a safe and effective preventative therapy for bloodstream infections in hematological cancer patients. SNIPR001 has been granted a Fast-Track designation for the indication "Prophylaxis of bloodstream E. coli infections in patients with hematological malignancy at risk of neutropenia" from the US Food and Drug Administration ("FDA"). SNIPR001 is also being developed to directly treat active *E. coli* infections.

About SNIPR BIOME

SNIPR Biome is a Danish clinical-stage biotech company pioneering the development of precision medicines using CRISPR technology for microbial gene therapy. We are pioneering a novel use of CRISPR/Cas technology to better treat and prevent human diseases through precision killing of bacteria or gene modification. SNIPR Biome was the first company to orally dose humans with a CRISPR therapeutic and the first company to have been granted US and European patents for the use of CRISPR for targeting microbiomes. SNIPR technology is used in collaborations with Novo Nordisk A/S, CARB-X, SPRIN-D, and MD Anderson Cancer Center. For more information, visit www.sniprbiome.com and follow us on LinkedIn and X.

About CARB-X

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) is a global non-profit partnership dedicated to supporting early-stage antibacterial research and development to address the rising threat of drug-resistant bacteria. CARB-X supports innovative therapeutics, preventatives and rapid diagnostics. CARB-X is led by Boston University and funded by a consortium of governments and foundations. CARB-X funds only projects that target drug-resistant bacteria highlighted on the CDC's

[2] Gencay, Y.E., Jasinskytė, D., Robert, C. et al. Engineered phage with antibacterial CRISPR–Cas selectively reduce *E. coli* burden in mice. Nat Biotechnol (2023). https://doi.org/10.1038/s41587-023-01759-y

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. https://carb-x.org/ | X (formerly Twitter) @CARB_X

Contact
ICR Consilium
Tracy Cheung, Chris Welsh, Davide Salvi
SNIPR@consilium-comms.com

SNIPR Biome
Dr Christian Grøndahl, Co-founder and CEO
contact@sniprbiome.com
www.sniprbiome.com