

## **SNIPR BIOME Announces FDA Clearance of Investigational New Drug (IND) Application for SNIPR001, a Novel CRISPR Therapy Targeting Life-Threatening *E. coli* Infections**

Copenhagen, January 11th, 2022: SNIPR BIOME ApS, a leading CRISPR and microbiome biotechnology company, is pleased to announce that the US Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) Application, for our first development candidate, enabling the company to initiate the first clinical trial in humans with SNIPR001. The trial, which is scheduled to begin in first half of 2022, will investigate safety and tolerability in healthy volunteers, and investigate the effect of SNIPR001 on *E. coli* colonisation in the gut.

*“The SNIPR BIOME team is excited about this important milestone, and we are looking forward to initiating the clinical trial in the US later this year, testing our unique CRISPR technology. SNIPR001 is our most progressed asset, and we are very proud of the team effort that brought us here”* says Dr. Christian Grøndahl, Co-founder & CEO.

The clinical trial could pave the way for a new type of precision therapy to selectively target *E. coli* in cancer patients with hematological malignancies - which are cancers that affect the blood, bone marrow, and lymph nodes. These patients are at increased risk of life-threatening bloodstream infections due to the disease, to chemotherapy treatment and, importantly, to pathogen translocation from the gut, in which *E. coli* is one of the most important players in causing infection.

SNIPR001 aims to target *E. coli* bacteria in the gut, and thereby prevent the translocation of these bacteria to the bloodstream, while leaving the commensal bacteria in the patient’s microbiome unaffected. The approach with SNIPR001 is harnessing a novel application of our proprietary CRISPR/Cas technology to selectively eradicate *E. coli* bacteria from the gut. 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.

*“Based on our pre-clinical data with SNIPR001 we believe that our technology holds a huge potential in designing tomorrow’s CRISPR-based medicines against life-threatening infections and to modulate microbiome-associated diseases”* says Dr. Milan Zdravkovic, Chief Medical Officer and Head of R&D at SNIPR Biome. *“With the rise in anti-microbial resistance there is an urgent need for novel drug candidates to treat infectious bacteria, such as *E. coli*, and we are grateful for the collaboration with the non-profit organisation, CARB-X on SNIPR001”*.

SNIPR001 is the first of many potential therapeutic candidates, as highlighted by Dr. Christian Grøndahl: *“We are building a strong pipeline of novel CRISPR assets and have beyond our interest in infectious diseases, collaborations with the MD Anderson Cancer Center on immuno-oncology, and with Novo Nordisk on applying gene-modulation technologies on the microbiome. We are excited to explore the full potential of our CRISPR technology in the future”*.

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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-threatening 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](http://www.sniprbiome.com)

### **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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