

SNIPR Biome reports positive clinical interim results for groundbreaking, first-in-human, CRISPR-based microbial gene therapy

- *SNIPR001 demonstrates proof of principle in reducing *E. coli* levels in the human gastrointestinal tract*
- *SNIPR001 is a novel CRISPR-Cas therapeutic, selectively targeting antibiotic-resistant *E. coli* which can cause fatal infections in vulnerable hematological cancer patients*
- *Future studies needed to evaluate the impact of SNIPR001 on reducing the rate of *E. coli* infections in high-risk cancer patients*

Copenhagen, May 31, 2023: SNIPR Biome ApS (“SNIPR”), the company pioneering CRISPR-based microbial gene therapy, today announces positive interim clinical results from its Phase 1 clinical trial with SNIPR001, the first CRISPR-armed phage therapeutic developed to specifically target and remove *E. coli*, including antibiotic-resistant strains, from the human gastrointestinal tract.

The work was supported by CARB-X, a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria, and the seminal research leading to the design of SNIPR001 was published in [Nature Biotechnology](#) earlier this month. The study, with 36 healthy individuals across three dose levels of SNIPR001, showed that oral dosing over seven days was well tolerated with only mild to moderate side effects and no withdrawals. Furthermore, SNIPR001 could be recovered in feces from treated individuals in a dose dependent manner, and treatment with SNIPR001 numerically lowered gut *E. coli* levels.

These findings demonstrate clinical proof of principle for this new technology, and future studies are now being planned to evaluate the impact of SNIPR001 on reducing the rate of infections in cancer patients at high risk of *E. coli* gut translocation into the bloodstream. SNIPR001 has the potential to prevent life-threatening bloodstream infections in over 35,000 cancer patients annually across the United States and Europe. In addition, the Phase 1 results support development of an intravenously administered version of SNIPR001, and clinical investigations for this therapy are being planned.

Dr Christian Grøndahl, CEO and co-founder of SNIPR Biome, commented: *“We are thrilled with these positive interim results from our Phase 1 clinical trial of SNIPR001, which provide clinical validation for this innovative treatment. With the combined killing effects of bacteriophages and CRISPR-Cas technology, SNIPR001 has demonstrated the ability to target and eliminate antibiotic-resistant *E. coli* strains in the gut, providing a safe alternative to traditional treatments that do not work against antibiotic-resistant strains, while sparing the rest of the gut microbiome. This is a significant milestone in our mission to develop groundbreaking solutions in the fight against antimicrobial resistance, and we look forward to advancing SNIPR001 through further clinical studies to learn more and ultimately, we hope, to improve patient outcomes.”*

The Phase 1 trial was conducted under a U.S. IND and involved 36 healthy adult volunteers, with 24 receiving three different dose levels of SNIPR001 and 12 receiving a placebo.

The objective of this study was to examine the safety profile, SNIPR001 recovery and pharmacodynamics of SNIPR001 (NCT05277350). SNIPR001 is initially being targeted at patients with hematological malignancies who are undergoing hematopoietic stem cell transplants and are vulnerable to bloodstream infections caused by translocation of *E. coli* from the gut. Fluoroquinolone is routinely used to address these bacteria but damages the gut microbiome and is ineffective against antibiotic-resistant bacteria. SNIPR001 is a cocktail of four CRISPR-armed phages that selectively target and eliminate *E. coli* that are resistant to fluoroquinolone. It can be used alone or in combination with



fluoroquinolone as a decolonization strategy. SNIPR001 has been granted a Fast Track designation by the U.S. Food and Drug Administration.

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About SNIPR BIOME

SNIPR Biome is a clinical-stage company developing precision medicines for vulnerable patients with difficult-to-treat conditions. We are pioneering a novel use of CRISPR/Cas technology to better treat and prevent human diseases through precision killing or the genetic modification of bacteria. SNIPR Biome is a leader in this transformational area of science, with a clinical trial underway, strong IP, and a diverse and experienced team. We are the first company to orally dose humans with a CRISPR therapeutic and the first company to have been granted a patent for the use of CRISPR for targeting microbiomes. Our technology is used in collaborations with CARB-X, MD Anderson Cancer Center and Novo Nordisk. SNIPR is headquartered in Copenhagen, Denmark. For more information, visit www.sniprbiome.com and follow us on [LinkedIn](#) and [Twitter](#).

About SNIPR001

SNIPR001 is a cocktail of four CRISPR-armed phages that selectively target and eliminate *E. coli* that are resistant to fluoroquinolone. It can be used alone or in combination with fluoroquinolone as a decolonization strategy. SNIPR001 has been granted a Fast Track designation by the U.S. Food and Drug Administration and is being developed with support from CARB-X. The seminal research leading to the design of SNIPR001 was published in [Nature Biotechnology](#) in May 2023.

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