



PRESS RELEASE

SoftOx Solutions AS: SIS-03 DOSE-ESCALATION PHASE COMPLETED AND INITIATION OF PROOF-OF-CONCEPT PHASE

SIS-03 advances toward the proof-of-concept patient phase in chronic airway infections

Oslo/Copenhagen – 8 June 2026 – SoftOx Solutions AS (“SoftOx”), a clinical-stage pharmaceutical company developing a novel anti-infective therapy for airway infections, today announces that the dose-escalation part of the SIS-03 Phase 2a clinical program has been completed. Following completion of this part of the trial, the Company has initiated the proof-of-concept (“PoC”) patient phase of the program. The objective of SIS-03 is to evaluate SoftOx Inhalation Solution (“SIS”) as an inhaled anti-infective therapy for chronic airway infections in patients with cystic fibrosis.

The completed dose-escalation part was designed to confirm safety and tolerability at increasing dose levels in healthy volunteers and to support dose-level selection for the PoC patient phase of the trial. The trial was approved by the Danish Medicines Agency in December 2025, and the first volunteer was enrolled in the initial dose-escalation part of the study in March 2026. This first part of SIS-03 is now fully completed.



TRANSITION INTO THE PROOF-OF-CONCEPT PATIENT PHASE

“ It is very satisfying to see the SIS-03 trial advancing as planned. With the dose-escalation part now completed, we are eager to move into the next phase, where we will learn much more about how SIS performs in a highly relevant patient population suffering from chronic airway infections. Patients with cystic fibrosis frequently experience chronic lung infections that may become resistant to currently available therapies, and we believe SIS has the potential to make a meaningful difference in a patient population where there remains a significant unmet medical need.”

Thomas Bjarnsholt, CEO of SoftOx

KEY MILESTONES ACHIEVED AND NEXT STEPS



DOSE-ESCALATION COMPLETED

The first part of the SIS-03 program is now fully completed.



PROOF-OF-CONCEPT PHASE INITIATED

The PoC patient phase is now ongoing.



FOCUS ON BACTERIAL LOAD REDUCTION

Assessing microbiological signals in patients' airways.



ADDRESSING A LARGE MEDICAL NEED

Potential to impact patients with CF and non-CF bronchiectasis.

The initiation of the PoC patient phase marks an important next step for the SIS-03 program. This upcoming phase is designed to assess microbiological signals relevant to establishing proof-of-concept for SIS, including key data on bacterial load reduction in patients' airways.

A separate topline safety update from the dose-escalation part of SIS-03 is expected to be communicated when the relevant data analysis has been completed. Therefore, no detailed safety or tolerability data are disclosed in this announcement.

The SIS-03 clinical trial program is being conducted together with Rigshospitalet in Copenhagen, Denmark, and the upcoming proof-of-concept phase is expected to conclude in H1 2027.

SIS-03 remains separate from the Company's other ongoing SIS-02 clinical program.



ABOUT SIS



SoftOx Solutions AS is developing SIS, a novel inhaled anti-infective therapy for respiratory infections in the airways and lungs. SIS targets biofilm-associated infections through a patented, non-antibiotic mechanism designed to reduce the risk of resistance development.

Delivered by nebulizer, SIS is being developed to address bacterial, viral, and fungal pathogens through local delivery directly at the site of infection, without systemic exposure to the remainder of the human body.

Its broad pathogen relevance positions SIS as a distinct therapeutic in respiratory infections.



ABOUT SOFTOX SOLUTIONS AS

SoftOx Solutions AS (ticker: SOFTX) is a clinical-stage pharmaceutical company developing SIS (SoftOx Inhalation Solution), a novel inhaled anti-infective therapy for the treatment of respiratory infections in the airways and lungs.

The Company is listed on Euronext Growth Oslo.



POTENTIAL COMMERCIAL RELEVANCE IN CHRONIC AIRWAYS INFECTIONS



~13,000 patients with cystic fibrosis across the US and EU4+UK receive chronic inhaled antibiotic therapy



>USD 600 million annual market (CF & EU4+UK)



>USD 5 billion total potential market opportunity (CF & non-CF bronchiectasis)

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SOFTOX

INNOVATING RESPIRATORY HEALTH
Targeted anti-infective therapy for
Airway and Lung Infections