



FIRST PATIENT DOSED IN SIS-03 PROOF-OF-CONCEPT PATIENT TRIAL

First patient with chronic airway infection dosed,
marking initiation of the proof-of-concept phase



FIRST PATIENT DOSED IN THE SIS-03 PROOF-OF-CONCEPT PHASE

SoftOx Solutions AS ("SoftOx"), a clinical-stage pharmaceutical company developing a novel anti-infective therapy for airway infections, today announces that the first patient has been dosed in the proof-of-concept (PoC) patient phase of the SIS-03 clinical program.

This Phase 2a patient phase of the trial is evaluating SoftOx Inhalation Solution ("SIS") as an inhaled anti-infective therapy for chronic airway infections in patients with cystic fibrosis.

The dosing of the first patient follows the previously announced completion of the SIS-03 dose-escalation phase in healthy volunteers and the positive topline safety review, which reported no serious adverse events and no severe tolerability issues.

The PoC patient phase is designed to assess clinical and microbiological signals relevant to establishing proof-of-concept for SIS, including data on bacterial load reduction in patients' airways.



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Dosing the first patient in the SIS-03 proof-of-concept phase is a very important moment for SoftOx. For the first time, we are evaluating SIS directly in patients suffering from chronic airway infections – a population where existing therapies often fall short due to antimicrobial resistance. We look forward to generating clinical data that will help us understand the potential of SIS in this setting.

Thomas Bjarnsholt, CEO of SoftOx

The SIS-03 clinical trial program is being conducted in collaboration with Rigshospitalet in Copenhagen, Denmark. The Company expects to dose between 15 and 25 patients in this phase of the program, which is expected to conclude in H1 2027.

SIS-03 remains separate from the Company's other ongoing SIS-02 clinical program, which is evaluating SIS in healthy volunteers in a biodefence context.

The Company will provide further updates on SIS-03 as relevant milestones are reached.



POTENTIAL COMMERCIAL RELEVANCE IN CHRONIC AIRWAY INFECTIONS



Total potential
market opportunity



~13,000 patients with
cystic fibrosis across the US
and EU4+UK



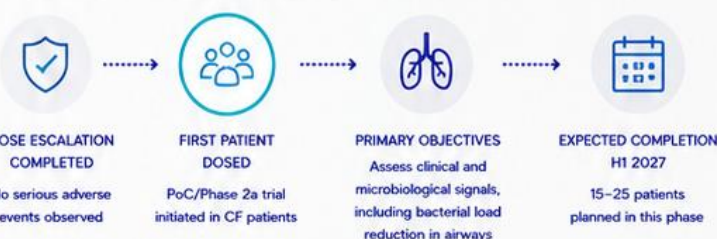
~445,000 patients with
non-CF bronchiectasis



>USD 600 million annual market
(CF & non-CF bronchiectasis)

>USD 5 billion total potential
market opportunity

SIS-03 CLINICAL PROGRAM STATUS



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 also exploring the potential dual-use relevance of SIS within civilian health security and biological preparedness. SoftOx is listed on Euronext Growth Oslo.



This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act. Figures, conceptual models, and selected visual elements have been developed using AI-assisted visualization tools to support communication of scientific, strategic, and operational concepts.

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SOFTOX

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