



SOFTOX

SOLUTIONS

PRESS RELEASE

SoftOx Solutions AS: FIRST PARTICIPANT ENROLLED IN BIODEFENCE-FOCUSED SIS-02 PHASE 1 CLINICAL STUDY

First participant enrolled, marking the initiation of SIS-02 and supporting the Company's respiratory infection and dual-use preparedness strategy.

Oslo/Dublin – 5 June 2026 – SoftOx Solutions AS ("SoftOx"), a clinical-stage pharmaceutical company developing a novel anti-infective therapy for airway infections, today announces that the first participant has been enrolled in the SIS-02 Phase 1 clinical study in Ireland. The enrolment follows the previously announced approval of the SIS-02 clinical trial application by Ireland's Health Products Regulatory Authority (HPRA) and marks the formal initiation of the study.




TWO ONGOING CLINICAL TRIALS NOW ADVANCING IN PARALLEL

The SIS-02 Phase 1 study is designed to evaluate the safety, tolerability, and pulmonary exposure profile of SoftOx Inhalation Solution ("SIS") following inhaled administration in healthy volunteers and supports the continued development of SIS for defence and biological countermeasure applications.

The initiation of SIS-02 represents an important operational milestone for SoftOx and expands the Company's clinical trial pipeline from one to two ongoing clinical studies. SIS-02 is separate from, and independent of, the Company's SIS-03 study in chronic lung infections in patients, including cystic fibrosis. Together, the two SIS programs support SoftOx's strategy to develop SIS as an inhaled anti-infective therapy with potential relevance in both civilian healthcare and defence-related biological preparedness.

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The initiation of SIS-02 is an important milestone for SoftOx. With trials now underway in both SIS-02 and SIS-03, we are continuing to build the human safety and exposure foundation for SIS as a novel inhaled anti-infective therapy.

In parallel with its potential clinical relevance in respiratory infections, we believe SIS may have a role to play in future national biological preparedness and health security strategies.”

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Thomas Bjarnsholt, CEO of SoftOx



SUPPORTED THROUGH THE EUROPEAN DEFENCE FUND COUNTERACT PROGRAM

The SIS-02 program is formally conducted through SoftOx's wholly owned subsidiary, SoftOx Solutions AS, and is grant-funded through SoftOx's participation in the COUNTERACT Consortium, which is funded by the European Defence Fund and includes universities, public research institutes, and companies across Europe. The program is also supported by the Norwegian Ministry of Defence.

The SIS-02 study is intended to add to the clinical evidence base for SIS and support the planning of subsequent development activities.

SoftOx will provide further updates on SIS-02 as the study progresses and when relevant data reviews have been completed.




ABOUT SIS
 SoftOx Solutions AS is developing SIS, a novel inhaled anti-infective therapy for respiratory infections in the airways and lungs. Delivered by nebulizer, SIS is being developed to address bacterial, viral, and fungal pathogens through local delivery directly at the site of infection while minimizing systemic exposure. Its broad pathogen relevance positions SIS as a distinct therapeutic platform 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.

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