INVESTOR UPDATE

First Subject Dosed in Combined Phase 2a Dose-Escalation and Proof-of-Concept Trial (SIS-03)

Oslo / Copenhagen: SoftOx Solutions AS ("SoftOx") today announces that First Subject First Dosing (FSFD) has been successfully completed in the SIS-03 clinical trial in Denmark. This milestone marks the operational initiation of the previously approved combined Phase 2a dose-escalation and proof-of-concept (PoC) study of SoftOx Inhalation Solution (SIS) and represents a key step toward the Company's next defined value inflection point.

SIS-03 is the regulatory-approved Phase 2a study approved by the Danish Medicines Agency and structured as a combined clinical program consisting of:

- A dose-escalation component designed to confirm safety and tolerability at increasing dose levels
- A proof-of-concept (PoC) component in people with cystic fibrosis (CF), assessing safety at higher doses and generating key data on bacterial load reduction in the CF airway environment

With first dosing now achieved, the program has transitioned from regulatory clearance to active clinical execution. Importantly, the study is supplied with a GMP-manufactured drug product produced from the previously announced GMP drug substance, confirming full CMC readiness and removing manufacturing risk from the Phase 2a pathway.

Advancing Toward a Defined Value Inflection Point

The combined study structure enables SoftOx to advance safety confirmation and early patient evaluation within a single integrated framework. The dose-escalation phase acts as a gating step toward the PoC component, ensuring a disciplined and capital-efficient development trajectory.

Data generated from SIS-03 are expected to:

- Confirm tolerability at escalated dose levels
- Provide first patient-based signals on bacterial load reduction in CF

Commercial Relevance

Cystic fibrosis represents a well-established market for chronic inhaled antimicrobial therapy, with approximately 13,000 patients across the US and EU4+UK currently receiving treatment, corresponding to an annual market exceeding USD 600 million.

Beyond CF, the same biofilm-targeting mechanism of SIS is applicable to significantly larger respiratory indications, including non-CF bronchiectasis, affecting approximately 445,000 treatable patients across the US and Europe and representing a multi-billion USD annual market opportunity.

The Phase 2a readout is therefore expected not only to validate the clinical profile of SIS in CF, but also to materially strengthen the strategic and commercial positioning of the platform across broader respiratory indications.

Upcoming Milestones

- 1H 2026: Dose-escalation topline data
- Q1 2027: Final Phase 2a PoC readout

These milestones represent clearly defined catalysts for the Company.

CEO Thomas Bjarnsholt comments:

"First dosing in SIS-03 marks the operational start of our combined Phase 2a program. With regulatory approval secured and GMP manufacturing successfully completed, we are executing according to plan. The upcoming dose-escalation and PoC readouts represent important milestones as we advance SIS toward later-stage development and strategic partnering."

Following FSFD, SoftOx will continue enrolment and dose escalation in accordance with the approved protocol. Further clinical updates will be communicated to the market as appropriate.

About SoftOx Solutions AS:

SoftOx Solutions AS (ticker: SOFTX) is a clinical-stage pharmaceutical company listed on Euronext Growth Oslo. The company is developing highly effective pan-antimicrobial pharmaceuticals targeting bacteria, viruses, and fungi. The technology is based on extensive research and development in partnership with leading Nordic research institutes.

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