INVESTOR UPDATE

HPRA Approves SIS-02 Phase 1 Trial, Strengthening Dual-Use and Preparedness Strategy

Oslo / Dublin: SoftOx Defense Solutions AS ("SoftOx") announces that the Health Products Regulatory Authority (HPRA) in Ireland has approved the Company's clinical trial application (CTA) for the SIS-02 Phase 1 clinical study in healthy volunteers.

The SIS-02 study will evaluate the safety, tolerability, and pulmonary exposure profile of SoftOx's inhalation solution. The approval represents a critical execution milestone, transitioning SIS into controlled human testing and establishing the human safety and dosing foundation required for both civilian development and preparedness-oriented pathways, including defence and biological countermeasure applications.

Strategic and Scientific Significance
Approval of SIS-02 confirms the readiness of SoftOx's inhalation platform for human clinical evaluation and validates the Company's development capabilities across GMP manufacturing, regulatory documentation, and clinical execution.

Conducting SIS-02 enables SoftOx to:
- Establish robust human safety and tolerability data
- Characterize pulmonary dose and exposure
- Generate foundational human data required for emergency-use and preparedness-relevant development routes

Business Implications: Parallel Clinical and Preparedness Execution
With the approval of SIS-02, SoftOx now has two regulatory-approved clinical trials, following the previously announced Phase 2a approval by the Danish Medicines Agency.

This positions the Company to move from sequential development into parallel execution, including:
- Phase 1 human safety and exposure (Ireland)
- Phase 2a dose escalation and early proof-of-concept in cystic fibrosis (Denmark)

The establishment of human safety and dosing data across these programs also enables SoftOx to consider programs for Dual-use and preparedness-oriented development activities in parallel with clinical execution.

Value and Relevance for Dual-Use and Biodefence Preparedness
SoftOx's SIS platform is being developed as a broad-spectrum, non-antibiotic inhaled therapeutic with attributes relevant to modern biodefence and medical countermeasure strategies, including:
- Activity against bacteria, viruses, and fungi addressing diverse airborne biological threats
- Low risk of resistance development, preserving long-term effectiveness and deployment flexibility
- Local airway administration enabling rapid onset at the primary site of exposure
- Scalable manufacturing and formulation stability are potentially compatible with stockpiling and rapid deployment frameworks

These attributes create potential optionality for future preparedness-oriented development pathways, contingent upon clinical validation and strategic or non-dilutive funding support.

If pursued, this would enable the SIS platform to address both chronic respiratory disease and defence-relevant biological threats within national resilience and pandemic response architectures.

While the dual-use profile thus enhances the long-term commercial flexibility of the platform, it does not alter the current clinical development focus, nor jeopardize the financial discipline applied in execution.

CEO Thomas Bjarnsholt comments:
"The approval of SIS-02 by HPRA in Ireland is a key execution milestone for SoftOx. It establishes the human safety and dosing foundation of our inhalation platform and, together with our already approved Phase 2a program, enables us to advance civilian development while progressing preparedness-oriented and defence-relevant applications in parallel."

Next step
Following approval, SoftOx will proceed with clinical site initiation and dosing of healthy volunteers in accordance with the approved protocol.

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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