SOF-SKN™ to progress to extension study in CLE patients

Highlights

- **Lead clinical asset for the treatment of autoimmune skin diseases to progress to extension clinical study in patients with cutaneous lupus erythematosus (CLE)**
- **SOF-SKN™ study planned to commence in Australia in Q1 CY27**
- **Approximately 15 CLE patients to be enrolled, each receiving 14 days of daily topical dosing with SOF-SKN, plus 7-day follow-up period.**
- **Initial efficacy signals expected Q2 CY27; full clinical data readout (efficacy signals plus safety and tolerability data) anticipated Q4 CY27**
- **Study to assess safety, tolerability and initial efficacy signals in CLE patients following successful Phase I HERACLES trial**
- **A/Prof Amanda Saracino, a specialist dermatologist in autoimmune skin disease with a research focus on lupus, to act as Lead Investigator for the planned study**
- **CLE represents a potential Orphan Drug Designation opportunity for SOF-SKN, given no current targeted therapies**

Sydney, 14 September 2026: Australian clinical-stage biotechnology company Noxopharm Limited (ASX:NOX) is pleased to provide an update on the clinical development program for its lead asset SOF-SKN, developed using a proprietary Sofra™ platform that translates naturally occurring immune control into targeted medicines.

A first in human (FIH) trial using SOF-SKN as a topical treatment was successfully completed in healthy volunteers in January 2026 (HERACLES Phase I), and the company is now preparing to commence an extension clinical study in patients with cutaneous lupus erythematosus (CLE) in Melbourne, Australia. Subject to completing regulatory and contractual requirements, including ethics approval, patient enrolment will commence in the first quarter of calendar year 2027 (Q1 CY27).

Lupus is an autoimmune disease than can affect different organs, and CLE is a sub-type of lupus that manifests in the skin. There is no current targeted therapy for treating CLE, and there is a significant unmet need for targeted and well tolerated therapies, as well as the opportunity for Orphan Drug Designation. The global market was valued at US5.4 billion in 2024.

The extension study is intended to assess the safety and tolerability of SOF-SKN in CLE patients, and to generate initial signals of clinical efficacy. The study is designed to enrol approximately 15 CLE patients, each receiving 14 days of daily topical dosing with SOF-SKN, plus a 7-day follow-up.

After the commencement of first patient treatment in Q1 CY27, Noxopharm expects to complete patient recruitment and treatment, and report initial efficacy signals, in Q2 CY27.

A full clinical data readout, comprising efficacy signals together with safety and tolerability data, is anticipated in Q4 CY27.

Data from the study is intended to inform the design of Noxopharm's planned Phase II clinical trial in CLE patients, targeted for H1 CY28, subject to regulatory feedback and standard clinical and manufacturing requirements.

Associate Professor Amanda Saracino, Lead Investigator for the planned study, is a clinical and academic dermatologist specialising in autoimmune connective tissue diseases and skin manifestations of autoimmune disease. She is a respected authority in the field and leads specialist clinics and a broad array of research activities in Melbourne.

A/Prof Saracino commented on the planned study, saying: "As a clinician who regularly treats people with lupus and other skin diseases, I am eager to assess SOF-SKN in patients with CLE. While SOF-SKN uses a well-recognised signalling pathway (TLR7/8 inhibition) for therapies in development for autoimmune conditions, its novel topical delivery approach has the potential to offer hope to CLE patients and others with a variety of chronic inflammatory skin diseases."

The broader Sofra™ technology platform is also being explored across other diseases associated with immune-system dysregulation.

Noxopharm CEO Dr Olivier Laczka has approved the release of this document to the market on behalf of the Board of Directors.

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About Noxopharm

Noxopharm Limited (ASX:NOX) is a clinical-stage Australian biotech company developing novel, targeted therapies for chronic inflammation, autoimmune diseases and cancer.

Noxopharm's proprietary Sofra™ platform is designed to regulate innate immune signalling with greater precision. Its lead clinical asset, SOF-SKN™, is a topical therapy initially being developed for

cutaneous lupus erythematosus, with Phase I completed and further clinical development progressing.

Beyond SOF-SKN, the Sofra platform supports a broader pipeline of internal and externally collaborated programs across inflammatory and autoimmune diseases, RNA therapeutics and oncology.

To learn more, please visit: noxopharm.com

About the Sofra technology platform

Developed from a breakthrough discovery in innate immunology, the Sofra technology platform represents a revolutionary approach to drug design by translating a new understanding of innate biology into targeted therapeutics that enable precision control of disease-relevant signalling.

Sofra is based on the use of synthetic nucleic acids, known as oligonucleotides, to mimic natural regulators of the body's defence system.

This novel approach enables selective and modular tuning of immune sensors, reducing or stimulating their associated biological responses to mitigate a broad range of diseases and enhance RNA-based therapies and emerging therapeutic technologies.

Sofra is focused on inflammatory and autoimmune diseases such as rheumatoid arthritis, lupus and diabetes, as well as immuno-oncology for cancer treatment. The global autoimmune disease therapeutics market was worth US$163.2 billion in 2024 and is expected to reach US$219.6 billion by 2035, while the worldwide immuno-oncology market was US$43 billion in 2023 and is projected to hit US$284 billion by 2033.

Further information and animations: SOF-SKN / SOF-VAC

Forward Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as "aim", "anticipate", "assume", "believe", "continue", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "plan", "should", "target", "will" or "would" or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company's control (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.