



HERACLES clinical trial successfully completed

Highlights

- **Second and final multiple-dose cohort finished**
- **No clinically relevant issues found**
- **Phase II-enabling studies set to begin**

Sydney, 21 January 2026: Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce the second and final multiple-dose cohort of [SOF-SKN™](#) has been finished in the HERACLES trial.

The Safety Steering Committee has determined the treatment to be safe and well tolerated, with no clinically relevant issues found.

This means the entire clinical part of the HERACLES trial has now successfully concluded, with a highly positive safety outcome for all dosing groups.

The trial has progressed rapidly from its recruitment phase through every single-dose and multiple-dose cohort to its conclusion, and saw high levels of participant compliance with the dosing regimen and the application of SOF-SKN.

This represents a significant achievement from everyone involved, and Noxopharm would like to thank the teams at Doherty Clinical Trials, as well as the contract research organisation and Hudson Institute of Medical Research, for their professionalism and ongoing support.

Following this positive safety outcome, the company expects to begin Phase II-enabling studies and drug scale-up processes in the near future.

Noxopharm CEO Dr Gisela Mautner said: “The primary goal of the trial was to make sure that SOF-SKN is safe over a variety of different applications of the cream, and to investigate how well participants tolerated the drug. We have passed both aspects with flying colours, and I’m very proud of the way we have delivered this trial over the past few months. We now move on to preparing for our next goal, which is to test SOF-SKN on lupus patients.”

SOF-SKN is initially being developed for the chronic inflammation caused by the autoimmune disease cutaneous lupus erythematosus (CLE), before potential development for other autoimmune-related skin diseases like psoriasis and dermatomyositis. The global CLE market is worth more than US\$3.3 billion and is expected to grow significantly over the coming years. The core Sofra™ technology could also be further utilised for rheumatoid arthritis and diabetes, plus other diseases linked to the dysregulation of the immune system.

-ENDS-

About the Sofra technology platform

Developed from a [breakthrough discovery](#) in the immune system, Sofra comprises a novel class of drugs targeting inflammatory and autoimmune diseases, as well as RNA therapeutics and vaccines.

[Sofra technology](#) has potential applications in a wide range of diseases related to the immune system such as rheumatoid arthritis, lupus and diabetes, as well as other diseases like cancer.

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.

The proprietary platform is based on short nucleic acid sequences, the building blocks of DNA or RNA, known as oligonucleotides. These act on specific immune sensors to regulate inflammation at its source, reducing or stimulating it to control the disease. In essence, the Sofra technology for autoimmune diseases replicates what is naturally occurring in the bodies of healthy people, but is either absent or too little in patients with autoimmune conditions.

Further information and animations: [SOF-SKN](#) / [SOF-VAC](#)

About Noxopharm

Noxopharm Limited (ASX:NOX) is a clinical-stage Australian biotech company discovering and developing novel treatments for cancer and inflammation, including a pioneering technology to improve the safety profile of a wide range of mRNA medicines.

The company utilises specialist in-house capabilities and strategic partnerships with leading researchers to build a growing pipeline of new proprietary drugs based on two technology platforms – Sofra™ (inflammation, autoimmunity, mRNA drug enhancement, and oncology) and Chroma™ (oncology).

To learn more, please visit: noxopharm.com

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Dr Gisela Mautner, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

Forward Looking Statements

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