



HERACLES clinical trial – Update #4

Highlights

- **Fourth and last single-dose cohort completed**
- **Important milestone as SOF-SKN found safe and well tolerated at highest dose**
- **Global cutaneous lupus market worth over US\$3.3 billion**

Sydney, 8 September 2025: Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce the fourth and last single-dose cohort of SOF-SKN™ has been successfully completed in the HERACLES trial.

The safety steering committee has determined the fourth and highest dose level to be safe and well tolerated, with no clinically relevant issues found. This is an important milestone for [SOF-SKN™](#) as a novel drug candidate for autoimmune diseases being tested on people for the first time.

The HERACLES study aims to evaluate the safety and tolerability profile of SOF-SKN by testing it at four different concentrations, and is [taking place in Australia](#) to capitalise on Australian expertise in lupus research and early phase clinical trials. Noxopharm will also secure federal R&D tax benefits by conducting the study locally.

The fourth dose marks the successful conclusion of this single-dose part of the trial, which has seen SOF-SKN given to four cohorts, each with four participants receiving a single dose, and a schedule of dose increases from one cohort to the next.

Each cohort took approximately two weeks due to a battery of tests including electrocardiograms, physical exams, participant questionnaires, numerous blood tests, skin observation scoring tests and others. Tests were administered at multiple time points, with subsequent data collection and analysis.

Noxopharm CEO Dr Gisela Mautner said: “We are pleased to announce that we have cleared a crucial first hurdle in the development of SOF-SKN, and have shown that these initial doses are safe – an achievement that cannot ever be taken for granted in any drug trial.

“Given the success of this part of the trial and the absence of any safety concerns, we are now finalising our plans and will update shareholders soon on next steps for HERACLES.”

SOF-SKN is initially being developed for autoimmune diseases like cutaneous lupus erythematosus (CLE) before potential development for 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, type 1 diabetes, inflammatory bowel disease and other diseases linked to the dysregulation of the immune system, such as dementia.

-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

Investor, Corporate & Media enquiries:

Julian Elliott

M: 0425 840 071

E: julian.elliott@noxopharm.com

Company Secretary:

David Franks

T: +61 2 8072 1400

E: David.Franks@automicgroup.com.au

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

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 that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.