HERACLES clinical trial – Update #2

Highlights

- **Second dose cohort completed**
- **Next cohort to receive higher SOF-SKN™ dose**
- **Focus on safety, tolerability and dose finding**

Sydney, 11 August 2025: Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce the second dose cohort of SOF-SKN™ has been successfully completed in the HERACLES trial.

The safety steering committee has determined the second dose level to be safe and tolerable, with no clinically relevant issues found. The trial will therefore now proceed to the third cohort of participants, who will receive a higher dose.

HERACLES is a first-in-human trial for SOF-SKN™, a novel drug candidate for autoimmune diseases. The 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.

Dose finding

Incremental dose increases represent a standard approach for Phase 1 trials and have two main purposes: to minimise the risk for the participants, and to support the determination of the optimal dose to carry forward into subsequent clinical trials.

This stepwise approach derisks the SOF-SKN program and ensures the best possible data will be generated.

HERACLES protocol

The first part of the trial involves four cohorts, each with four participants receiving a single dose of SOF-SKN, and a schedule of dose increases from one cohort to the next.

Each cohort is scheduled to take approximately two weeks due to a battery of tests including electrocardiograms, physical exams, participant questionnaires, numerous blood tests, skin observation scoring tests and so on. All of these are administered at multiple time points, with subsequent data collection and analysis.

This data will then be evaluated and discussed by the safety steering committee, a panel of clinical and trial experts, before it can give the green light to proceed to the next cohort and a higher dose.

Importance of safety trials
In the drug development process, a clean safety profile is of paramount importance as any new drug can potentially have safety issues that could halt further development.

Regulatory authorities have strict safety approval processes for when new drugs are allowed to be given to people and require extensive evidence that limits, as much as possible, the toxicity risk to clinical trial participants. This is particularly important given around 30% of new drugs fail during trials due to unmanageable toxicity.*

Ultimately the approval of any drug involves regulators weighing up two main criteria: safety issues such as the seriousness of side effects, and the benefit patients get from the drug. Safety therefore becomes one of the two main aspects that affect whether a drug will eventually be approved and make it to market.

Market opportunity
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 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.

The global CLE market is worth more than US$3.3 billion and is expected to grow significantly over the coming years.

* *https://pmc.ncbi.nlm.nih.gov/articles/PMC9293739/*

-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.

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 (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.