



Clinical trial recruitment progressing rapidly

Highlights

- Identification and screening of HERACLES participants on schedule
- Trial team training and site preparations concluded
- SOF-SKN™ manufacturing completed

Sydney, 25 June 2025: Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce that recruitment activities are progressing rapidly and on schedule for the HERACLES clinical trial.

HERACLES is a first-in-human trial for [SOF-SKN™](#), a first-in-class drug candidate for autoimmune diseases. The study aims to evaluate the safety profile of SOF-SKN by testing it at four different concentrations, and will [take 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 recruitment phase involves a wide array of activities such as advertising the trial to potential subjects, as well as the identification, pre-screening, and later full screening of participants to ensure they meet all eligibility criteria before formal enrolment.

As part of the initial trial activities, representatives from Noxopharm, the team at Doherty Clinical Trials and other relevant parties have already completed their mandatory training. This ensured that those involved were trained on the protocol and on all study procedures – everything from the correct storage, dispensing and application of SOF-SKN to blood collection, overall evaluation of participants, and recording of data in a purpose-built database.

Additionally, Noxopharm has now finalised its SOF-SKN manufacturing and is in the last stages of quality control, while also confirming the drug is appropriately labelled and packaged to regulatory standards before being prepared for shipping to the trial site.

Noxopharm CEO Dr Gisela Mautner said: “Following our recent ethics approval, we are now moving full steam ahead as we work through the operational aspects of the trial. It’s great to see that recruitment activities and outreach to potential participants has been pleasingly fast, and we will keep shareholders updated as we move into the dosing stage.”

SOF-SKN is initially targeted at cutaneous lupus erythematosus (CLE) before potential development for autoimmune-related skin diseases like psoriasis and atopic dermatitis. 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.

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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

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.