



Green light for HERACLES clinical trial

Highlights

- Human Research Ethics Committee promptly approves trial
- Recruitment activities set to begin
- Australian first-in-human clinical trial of SOF-SKN™

Sydney, 29 May 2025: Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce it has been granted approval by the Human Research Ethics Committee for the HERACLES clinical trial following a straightforward review process.

HERACLES will be a first-in-human trial of [SOF-SKN™](#), a novel drug candidate for chronic inflammatory 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 research for inflammatory diseases such as lupus, as well as early phase clinical trials. Noxopharm will also secure federal R&D tax benefits by conducting the study locally.

The green light means the company will now work closely with the [Doherty Clinical Trials](#) team in Melbourne to quickly progress the operational aspects of the trial. These include activities such as undertaking site initiation, preparing and shipping the trial-specific batches of SOF-SKN, and screening and recruiting trial participants.

The Doherty Clinical Trials team has wide-ranging experience working with some of the world's leading clinical investigators and research scientists, and has a particular focus on early phase studies. It is renowned for its deep clinical trial knowledge, as well as its experience in infectious diseases and, most importantly, immunology.

Noxopharm CEO Dr Gisela Mautner said: "The granting of ethics approval for the first ever clinical trial from our Sofra™ technology platform is an important milestone. The quick approval is testament to the thorough preparation of the dossier by our team and also a very efficient review process by the committee, for which we are very grateful.

"Our team has rapidly developed this drug, successfully navigated its way through extensive preclinical testing, and prepared a robust data package that has now culminated in the trial. We have a lot of work in front of us, but we have planned everything in great detail and will be able to start the trial very quickly. It's an exciting time, and we will of course keep shareholders updated as these activities progress."

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

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