



Noxopharm clinical trial submission

Highlights

- Application submitted to Human Research Ethics Committee
- Move follows successful preclinical testing
- Australian first-in-human clinical trial for SOF-SKN™

Sydney, 2 May 2025: Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce that following successful preclinical testing, it has now applied for Human Research Ethics Committee (HREC) approval for the HERACLES clinical trial.

This is a necessary and important regulatory step in Australia's clinical trials process, as HRECs review research proposals that involve human participants to ensure they meet ethical standards and guidelines, including the [National Statement on Ethical Conduct in Human Research](#).

The submission of a comprehensive preclinical data package, the clinical protocol and other supporting documentation will be reviewed by the HREC, and a decision is expected after a review period of several weeks. Noxopharm will keep shareholders informed of the outcome in a timely fashion.

The HERACLES clinical trial will be a first-in-human trial for [SOF-SKN™](#), a novel 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.

SOF-SKN is initially targeted at cutaneous lupus erythematosus (CLE) as a proof of concept before potential development for autoimmune-related skin diseases like psoriasis and atopic dermatitis. The core Sofra technology could also be developed for rheumatoid arthritis, type 1 diabetes, inflammatory bowel disease and other diseases linked to the dysregulation of the immune system, such as dementia.

Noxopharm CEO Dr Gisela Mautner said: "The preclinical testing phase has gone extremely well. We have been able to advance our program expeditiously and are pleased to file our ethics application so we can start the HERACLES clinical trial. The team has worked very hard to get to this point, which reflects our determination to progress our Sofra™ technology as rapidly as we can."

-ENDS-



About Noxopharm

Noxopharm Limited (ASX:NOX) is an innovative Australian biotech company discovering and developing novel treatments for cancer and inflammation, including a pioneering technology to enhance 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.