



## SOF-SKN™ successfully passes final pre-trial study

### Highlights

- Last required regulatory *in vivo* study successfully completed
- No safety issues identified
- Paves way for Human Research Ethics Committee submission

**Sydney, 15 April 2025:** Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce its [SOF-SKN™](#) lupus medication has passed its final *in vivo* preclinical safety study ahead of regulatory submission for the upcoming HERACLES clinical trial.

As a necessary step prior to a Phase 1 trial, the study examined numerous safety and toxicity criteria to check there were no clinically relevant adverse effects, and that the drug would be considered safe to give to trial participants.

Beyond the standard clinical observations, the study involved a comprehensive battery of tests and measurements covering cardiac, respiratory and neurological functions, dermal toxicity, haematology, serum chemistry, toxicokinetics, and histopathology of all vital organs and tissues. The work was carried out according to stringent Good Laboratory Practice (GLP) international standards, which are necessary for assuring the quality and integrity of preclinical data as required by regulatory authorities.

No clinically relevant safety issues were identified.

Following this positive outcome, the next milestone is for the company to apply for Human Research Ethics Committee (HREC) approval for the clinical trial, which will be the final regulatory step before HERACLES can commence.

The HREC's decision will be made after a review period of several weeks, and the company will keep shareholders informed of the outcome in a timely fashion.

Noxopharm CEO Dr Gisela Mautner said: "These results mean we have now cleared the last preclinical testing milestone ahead of our ethics submission for the trial. The accelerated pace with which we have progressed SOF-SKN reflects our determination to explore the potential of this innovative technology in a clinical setting as quickly as possible.

"Our approach to investigating lupus in the clinic opens the way to potentially moving seamlessly into larger autoimmune disease markets beyond lupus such as rheumatoid arthritis, psoriasis, type 1 diabetes, inflammatory bowel disease and other inflammatory diseases linked to the dysregulation of the immune system, such as dementia."

Autoimmune diseases are illnesses that make the body mistakenly attack itself, and lupus is one of a wide range of these diseases that affect millions of people worldwide. Patient numbers have been steadily increasing over the past few decades, particularly in

Westernised societies, with approximately 10% of the global population affected. This means that around 780 million people worldwide are living with various autoimmune diseases.

The global market is expected to reach approximately USD 168 billion in 2025 and expand to around USD 226 billion by 2035, reflecting a compound annual growth rate of 3.0% over the forecast period.

**-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).

Noxopharm also has a major shareholding in US registered, Australia based Nyrada Inc (ASX: NYR), a drug discovery and development company specialising in novel small molecule therapies.

To learn more, please visit: [noxopharm.com](http://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.*

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### **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.