



FDA feedback supports SOF-SKN™ Phase II plans

Highlights

- FDA has provided constructive feedback which was supportive of Noxopharm's planned approach for a Phase II clinical trial for SOF-SKN™, its autoimmune disease drug candidate
- This feedback provides increased regulatory clarity and helps de-risk SOF-SKN's development pathway
- Noxopharm will incorporate this feedback into preparations for a future IND submission that has the potential to increase SOF-SKN's commercial attractiveness
- Phase II clinical trial targeted for H1 CY28, subject to regulatory, clinical and manufacturing requirements
- Orphan Drug Designation opportunity exists for SOF-SKN, given no current targeted therapies

Sydney, 8 October 2026: Australian clinical-stage biotechnology company Noxopharm Limited (ASX:NOX) has received constructive feedback from the US Food & Drug Administration regarding its planned Phase II clinical trial for [SOF-SKN™](#), the company's autoimmune disease drug candidate.

The feedback follows Noxopharm's [7 July 2026 announcement](#) that it had formally requested a pre-Investigational New Drug (IND) meeting with the FDA to discuss SOF-SKN's planned clinical development pathway and requirements for a future IND submission.

Through the pre-IND meeting process, the FDA formally provided its views on Noxopharm's planned clinical development pathway, along with topics such as clinical trial design, product manufacturing, non-clinical safety studies, and other critical requirements to support a comprehensive IND application.

At a high level, the FDA was supportive of Noxopharm's approach along with the company's proposal on how this novel technology could fit into the agency's regulatory framework. The feedback was particularly supportive of Noxopharm's chemical manufacturing strategy, and the agency also considered the proposed Phase II trial design as reasonable.

The FDA also provided technical guidance to ensure alignment with its expectations around the proposed non-clinical studies.

Noxopharm CEO Dr Olivier Laczka said: "Engagement with the FDA at this stage is a critical step in our progress along the clinical trials pathway. We appreciate the opportunity to get detailed feedback that will now feed into our Phase II preparations, and look forward to moving this project forward as quickly as possible."

This outcome is the result of several years of extensive strategic, research, and preparatory work undertaken in close collaboration with industry-leading regulatory experts regarding how the company would develop and present its novel [Sofra™](#) technology platform to the FDA. The learnings from this process may also help inform future regulatory planning for other Sofra-derived assets.

This early engagement with the US regulator also represents an important de-risking process. It allows Noxopharm to align with FDA guidance by incorporating the FDA's feedback into a planned series of substantive and highly relevant technical studies leading up to the trial.

The trial itself is targeted for H1 CY28, subject to regulatory feedback and standard clinical and manufacturing requirements. Noxopharm will also prepare for a future IND submission to support potential US clinical development. Progressing through the IND process could increase SOF-SKN's commercial potential and make the drug more attractive to industry in the US and elsewhere.

Noxopharm currently is in the final preparations for its extension study in patients with cutaneous lupus erythematosus (CLE) in Melbourne. Lupus is an autoimmune disease that can affect different organs, and CLE is a sub-type of lupus that manifests in the skin. There are currently no therapies specifically approved for treating CLE, and there is a significant unmet need for targeted and well-tolerated therapies, while SOF-SKN also represents a potential Orphan Drug Designation opportunity. The global market was valued at US\$5.4 billion in 2024.

Noxopharm CEO Dr Olivier Laczka has approved the release of this document to the market on behalf of the Board of Directors.

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About Noxopharm

Noxopharm Limited (ASX:NOX) is a clinical-stage Australian biotech company developing novel, targeted therapies for chronic inflammation, autoimmune diseases and cancer.

Noxopharm's proprietary Sofra™ platform is designed to regulate innate immune signalling with greater precision. Its lead clinical asset, SOF-SKN™, is a topical therapy initially being developed for

cutaneous lupus erythematosus, with Phase I completed and further clinical development progressing.

Beyond SOF-SKN, the Sofra platform supports a broader pipeline of internal and externally collaborated programs across inflammatory and autoimmune diseases, RNA therapeutics and oncology.

To learn more, please visit: noxopharm.com

About the Sofra technology platform

Developed from a [breakthrough discovery](#) in innate immunology, the Sofra technology platform represents a revolutionary approach to drug design by translating a new understanding of innate biology into targeted therapeutics that enable precision control of disease-relevant signalling.

Sofra is based on the use of synthetic nucleic acids, known as oligonucleotides, to mimic natural regulators of the body's defence system.

This novel approach enables selective and modular tuning of immune sensors, reducing or stimulating their associated biological responses to mitigate a broad range of diseases and enhance RNA-based therapies and emerging therapeutic technologies.

[Sofra](#) is focused on inflammatory and autoimmune diseases such as rheumatoid arthritis, lupus and diabetes, as well as immuno-oncology for cancer treatment. 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.

Further information and animations: [SOF-SKN](#) / [SOF-VAC](#)

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.