



Pre-IND meeting request with US FDA

Highlights

- **Important regulatory milestone**
- **Meeting in two months' time**
- **Supports SOF-SKN™ clinical pathway**

Sydney, 7 July 2026: Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce it has formally requested a pre-Investigational New Drug (IND) meeting with the US Food & Drug Administration.

Pre-IND meetings represent an important milestone in the drug development process. They involve a discussion of the planned clinical development pathway along with topics such as product manufacturing, quality controls, and other requirements to support a comprehensive IND application.

Noxopharm expects its meeting to occur in around two months' time, which will help de-risk the development of [SOF-SKN™](#), the company's autoimmune disease drug candidate, and also prepare for a future IND submission.

A successful application stands to increase SOF-SKN's commercial potential and make the drug more attractive to potential industry partners in both the US and elsewhere.

Noxopharm CEO Dr Olivier Laczka said: "Over the past few months we have worked hard to prepare our data package to take to the FDA, and are anticipating a constructive engagement with their team.

"While we continue to actively investigate prospects for a near-term pilot study in a local Australian patient population, progressing down the US regulatory pathway is a key component of our overall strategy to boost SOF-SKN's commercial attractiveness in the global marketplace."

SOF-SKN is initially being developed for the chronic inflammation caused by the autoimmune disease cutaneous lupus erythematosus (CLE), before potential expansion into additional autoimmune-related skin diseases such as psoriasis and dermatomyositis.

The global CLE market is worth more than US\$3.3 billion and is expected to grow significantly over the coming years. Beyond dermatology, the underlying Sofra technology may also support future development opportunities across a broader range of diseases associated with immune system dysregulation, including rheumatoid arthritis and diabetes.

-ENDS-

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](#)

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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Noxopharm CEO Dr Olivier Laczka 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.

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