



Noxopharm progresses US regulatory strategy

Highlights

- Preparations for US FDA pre-IND meeting
- Move to boost SOF-SKN™ commercial potential
- Specialist advice from global clinical research organisation

Sydney, 6 May 2026: Noxopharm Limited (ASX:NOX) has engaged a global clinical research organisation in the lead-up to a pre-Investigational New Drug (IND) meeting with the US Food & Drug Administration.

The move will provide support to Noxopharm in preparing a data package suitable for a meeting with the FDA to discuss the planned clinical development pathway and requirements to support an IND application for [SOF-SKN™](#).

Pre-IND meetings represent an important milestone in the drug development process and require significant planning. During the meetings companies can obtain feedback on the design of both preclinical studies and clinical trials, as well as product manufacturing and quality controls. The meeting is a strategic engagement with the US regulatory authority to optimally prepare for a subsequent IND application submission.

From Noxopharm's strategic perspective, securing a successful IND application would likely increase SOF-SKN's commercial potential and make the drug more attractive to potential industry partners in both the US and elsewhere.

To help streamline the regulatory process, the company has engaged [Novotech](#), a globally recognised full-service clinical research organisation (CRO) and scientific advisory company.

Noxopharm CEO Dr Olivier Laczka said: "Boosting SOF-SKN's attractiveness in the market is a top priority and engaging Novotech is an important step along this road from a regulatory perspective. A pre-IND meeting opens the way to a subsequent full IND application in the US, further demonstrating the robustness of our data and the genuine potential of both our drug candidate and our Sofra™ technology platform more broadly."

SOF-SKN is initially being developed for the chronic inflammation caused by the autoimmune disease cutaneous lupus erythematosus (CLE), before potential development for other autoimmune-related skin diseases like 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. The core Sofra™ technology could also be further utilised for rheumatoid arthritis and diabetes, plus other diseases linked to immune system dysregulation.

-ENDS-

About the Sofra technology platform

Developed from a [breakthrough discovery](#) in the immune system, Sofra comprises a novel class of drugs targeting inflammatory and autoimmune diseases, as well as RNA therapeutics and vaccines.

[Sofra technology](#) has potential applications in a wide range of diseases related to the immune system such as rheumatoid arthritis, lupus and diabetes, as well as other diseases like cancer.

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.

The proprietary platform is based on short nucleic acid sequences, the building blocks of DNA or RNA, known as oligonucleotides. These act on specific immune sensors to regulate inflammation at its source, reducing or stimulating it to control the disease.

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

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

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

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