



SOF-SKN manufacturer signed for HERACLES clinical trial

Highlights

- Specialist supplier to produce novel SOF-SKN drug
- Clinical trial preparations on schedule
- Unique drug candidate reduces inflammation

Sydney, 10 October 2024: Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce it has contracted a specialist supplier to manufacture SOF-SKN™ for the upcoming [HERACLES clinical trial](#).

[SOF-SKN](#) is a novel drug candidate for autoimmune diseases, specifically cutaneous lupus erythematosus (CLE), and the first-in-human trial is planned to start in early 2025.

The manufacturing contract involves highly specialised work to produce sufficient quantities of SOF-SKN at rigorous quality standards to support the trial. SOF-SKN contains a proprietary ultra-short oligonucleotide that binds to specific inflammation receptors in the body to reduce inflammation at its source.

It will take several months for enough drug to be prepared for the trial, with various advanced technical and purification processes utilised to ensure efficient production and robust quality control. This process will also involve Noxopharm having oversight of the full supply chain, including the procurement of high-quality raw materials that meet regulatory requirements at every step.

Once the active ingredient of the drug has been synthesized, it will then be combined with other non-active ingredients by the same manufacturer to produce the actual [SOF-SKN formulation](#) that will be applied to the skin of trial participants.

Noxopharm has a high level of evidence for the reliability of the manufacturer as this partner has been closely involved in earlier preclinical SOF-SKN studies, lowering risk at an important juncture in the trial preparations.

Providing further quality assurance, Noxopharm has extensively characterised the physical and chemical attributes of both the active and non-active ingredients in order to be able to produce a standardised and replicable product for patient use. Along with strict microbiological testing, this approach ensures that consistency and purity remain within stipulated limits, thereby meeting regulatory requirements and clinical standards.

Noxopharm is also currently in the process of selecting a Phase 1 trial unit, as well as undertaking the many other activities necessary to prepare for a trial in the heavily regulated clinical setting.



Noxopharm CEO Dr Gisela Mautner said: “Signing this contract is a commitment on our part that takes us a significant step closer to the clinic. Manufacturing such ultra-short oligonucleotides requires considerable expertise, and we are confident that our partner will deliver on time and to the high quality standards needed to support a trial in Australia.”

Autoimmune diseases are illnesses that make the body mistakenly attack itself, and lupus is just one of a wide range of these diseases that affect millions of people worldwide. Estimates of the number of individuals suffering from autoimmune diseases in the US alone range from 14 to 24 million cases, and the global immunology market is projected to grow from USD 92 billion in 2021 to USD 158 billion in 2028.

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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 mRNA vaccines.

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 – Chroma™ (oncology) and Sofra™ (inflammation, autoimmunity, and mRNA vaccine enhancement).

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

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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.

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.