



## First SOF-SKN™ dose in HERACLES clinical trial

### Highlights

- First trial participant receives novel treatment
- Focus on safety, tolerability and dose-finding
- Four cohorts at ascending doses
- Addressing unmet clinical needs in global US\$3 billion-plus lupus market

**Sydney, 16 July 2025:** Clinical-stage biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce a major milestone with the first SOF-SKN™ dose administered in the HERACLES trial.

HERACLES is a first-in-human trial for [SOF-SKN™](#), a novel drug candidate for autoimmune diseases. The study aims to evaluate the safety and tolerability profile of SOF-SKN by testing it at four different concentrations, and is [taking place in Australia](#) to capitalise on Australian expertise in lupus research and early phase clinical trials. Noxopharm will also secure federal R&D tax benefits by conducting the study locally.

Since [ethics approval](#) multiple teams have been diligently working on several critical tasks to reach first dosing. These activities include completing regulatory documentation, manufacturing, labelling and shipping the drug, developing and testing a trial-specific database, preparing the site for protocol-specific procedures, and recruiting participants into the trial.

This complex behind-the-scenes work is essential for ensuring that trial data will be accepted by local and global regulatory authorities.

The first part of the trial involves four cohorts each with four participants, and a schedule of dose increases from one cohort to the next. The first cohort is now receiving the lowest dose, then a safety steering committee meeting will be held to evaluate the data and determine the next step in the trial.

Noxopharm CEO Dr Gisela Mautner said: “This is a huge milestone for the company as we have taken our first Sofra drug candidate into the clinic at a rapid pace. To our knowledge, this is the first time a molecule that blocks TLR7/8 in a targeted manner has been used topically in humans, which makes it even more exciting.

“The global lupus market is worth more than US\$3 billion and is expected to grow significantly over the coming years.”

SOF-SKN is initially targeted at cutaneous lupus erythematosus (CLE) before potential development for autoimmune-related skin diseases like psoriasis and atopic dermatitis. The core Sofra™ technology could also be further utilised for rheumatoid arthritis, type 1

diabetes, inflammatory bowel disease and other diseases linked to the dysregulation of the immune system, such as dementia.

**-ENDS-**

#### **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](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.