Noxopharm Targets Clinical Trial for First-in-Class Drug

Highlights

- **First in-human clinical trial for SOF-SKN™ and Sofra™ platform**
- **Efficient trial design with expected early results**
- **Capitalises on Australian expertise**
- **Plan to leverage Sofra platform for wider markets**

Sydney, 19 August 2024: Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to announce its first in-human trial for SOF-SKN™, a novel drug candidate for autoimmune diseases.

The trial is planned to start in early calendar year 2025 and provide proof of concept for the skin disease that is caused by cutaneous lupus erythematosus (CLE).

The first in-human trial will be known as HERACLES (for '**H**arnessing **E**ndogenous **R**egulators **A**gainst **CLE S**tudy') and will take place in Australia to capitalise on Australian expertise in lupus research and early phase clinical trials. Holding the trial in Australia will also help the company maximise rebates from the Australian Government's R&D Tax Incentive scheme.

Noxopharm sees the development of SOF-SKN as just the first step in leveraging the enormous breadth of the Sofra™ platform to tackle the much larger autoimmune disease market in areas such as rheumatoid arthritis, for example.

As noted in its June 2024 quarterly update, Noxopharm's Sofra™ technology platform is attracting international industry attention and as a result, several material transfer agreements with mid-size to multi-billion dollar companies are already in place.

SOF-SKN is a first-in-class oligonucleotide TLR7/8 antagonist that has the potential to change the treatment paradigm of CLE from merely controlling symptoms to actually treating the disease itself right at the source.

Adopting an incremental and cost-effective approach to this first trial, HERACLES will be a high-potential, low-risk study focusing on safety and dose finding in healthy volunteers.

The trial itself will have two parts – the first will proceed sequentially and involve participants receiving a single dose of the drug, followed by a safety check, then a separate cohort of participants receiving a higher dose, followed by a safety check. This process will then continue until the maximum dose as approved by the ethics committee has been reached. The second part will involve several groups of volunteers, again in a sequential manner, each receiving multiple doses with appropriate safety checks at each stage.

The trial has been designed to be easily implemented and is expected to proceed rapidly. The first safety readouts are expected to be available four to six weeks after dosing has

finished, while a comprehensive data analysis should be completed in the fourth quarter of calendar year 2025.

As an essential part of the preparations, and following the recent scaling up of production to international quality standards, Noxopharm is now finalising the specific type of SOF-SKN formulation that will be used in the HERACLES trial via various technical studies.

The company is also 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 a heavily regulated clinical setting. These include designing a detailed trial protocol, preparing a dossier for ethics submission, developing an Investigator's Brochure and building the trial database.

Importantly, while the HERACLES trial is ongoing, the company plans a seamless transition to a follow-on trial targeting the treatment of lupus patients at a number of specialist centres in Australia.

Noxopharm CEO Dr Gisela Mautner said: "This trial marks the return of Noxopharm to the small group of ASX-listed Australian companies that have made it to the clinical trial stage. It is a major milestone that we have achieved in record time, and we are really pleased to be going back to the clinic with our first asset from the very promising Sofra platform.

"We have been methodical and thorough in our approach, and we will continue to comply with established and approved procedures of conducting clinical trials as we begin this important phase of the drug development journey. While there is still a lot of work ahead, we are pressing forward as rapidly as possible and in line with the strategy we have set out over the past 18 months.

"At the big picture level, we very much see this as just the first chapter in developing the Sofra platform across larger markets. We will make decisions with these ambitions in mind while continuing to introduce the huge potential of the platform to external stakeholders."

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.

There are very few lupus treatment options available. While corticosteroids and corticosteroid-like and anti-malarial drugs are often prescribed, they only treat the symptoms of the disease but do not affect the disease itself.

Lupus is most often diagnosed in young adults aged 15 to 45 years of age. Currently, there is no cure for skin lupus. Treatment of the symptoms is usually required on an ongoing or recurring basis, often for life, representing a significant commercial opportunity for any effective medication.

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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

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

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

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