Milestone reached as SOF-SKN™ progresses to next level

Highlights

- **Major drug development milestone reached**
- **100x scale-up of drug manufacture underway**
- **Next level of testing standards applied to ensure clinic readiness**
- **Large global market for SOF-SKN™ with need for lifelong treatments**

Sydney, 14 May 2024: Innovative biotech company **Noxopharm Limited (ASX:NOX)** is excited to announce it is scaling up production of its preclinical SOF-SKN™ lupus medication to the quality standards that will be required for upcoming regulatory submissions.

In a significant inflection point, SOF-SKN has now reached the next level of its development, meaning that much higher amounts of the drug will need to be manufactured.

More stringent regulations will also apply, with manufacturing and testing now being performed under international Good Laboratory Practice (GLP) standards. These stringent standards are necessary for assuring the quality and integrity of preclinical data, especially safety data, bringing it up to pharmaceutical grade levels in advance of submissions to key regulators before testing in patients.

Noxopharm has selected an optimised lead drug candidate and is accelerating the project through a 100-fold increase in the amount of drug being produced under GLP standards. The drug will then be used within GLP-accredited laboratories to conduct several regulatory safety studies that will take place in the coming weeks and months.

The company has also commenced work on formulation and optimal dosing to maximise SOF-SKN's efficacy and tolerability in patients with autoimmune disease.

It has engaged with a range of experts specialising in the supply of pharmacopeia compliant materials and reagents for synthesis and formulation, as well as experts in quality control to ensure that manufacturing of the active ingredient and formulated drug takes place according to set specifications. In addition, the company is collaborating closely with specialists to test the formulated drug in a range of *in vitro* and *in vivo* models in order to further refine the characteristics of the formulated drug and dose. Importantly, each of these tasks is being performed to GLP standards.

These milestones have been achieved in an expedited fashion due to a very experienced team, rigorous prioritisation, and a sharp focus on core regulatory requirements.

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.

Lupus is most often diagnosed in young adults aged 15 to 45 years of age. 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.

Noxopharm CEO Dr Gisela Mautner said: "Scaling up to GLP standards demonstrates that we have great confidence in SOF-SKN as a prospective treatment for lupus, based on a large body of robust data. Reaching this checkpoint in the development process increases the potential for external interest in our technology, as well as the asset's commercial value.

"This is a major step in the drug development process. SOF-SKN has a well-informed timeline in place and is now on a clear path towards formal engagement with regulatory authorities.

"On the big picture level, we see the development of SOF-SKN as the first step on the way to tackling the much larger autoimmune disease market in areas such as rheumatoid arthritis. There is huge potential contained within our Sofra platform pipeline, and we aim to fully exploit that position both now and well into the future."

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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

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