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Australia's Noxopharm scales up production of lupus medication

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Next level of testing standards applied to ensure clinic readiness



Australian biotech company Noxopharm 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.

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.

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.

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 $92 billion in 2021 to $158 billion in 2028.

Noxopharm CEO Dr Gisela Mautner said, "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."