

## **HERACLES** Clinical Trial

## A New Approach to Autoimmune Disease

HERACLES ('Harnessing Endogenous Regulators Against CLE Study') is the first-in-human trial for SOF-SKN™, a novel drug candidate for autoimmune diseases developed from Noxopharm's innovative Sofra™ technology platform.

The trial aims to provide initial safety and pharmacokinetic data for the skin disease that is caused by cutaneous lupus erythematosus (CLE).

The development of SOF-SKN is just the first step in leveraging the enormous breadth of the Sofra platform to tackle many other autoimmune diseases such as rheumatoid arthritis, in a sizeable global market that is expected to reach US\$185 billion by 2029.

## **Treatment at the Source**

SOF-SKN contains a proprietary ultra-short oligonucleotide that blocks the inflammatory sensors known as Toll-like receptors 7 and 8 (TLR7/8), which are overactivated in numerous autoimmune diseases.

This first-in-class drug candidate has the potential to change the treatment paradigm of CLE from merely controlling symptoms to actually treating the disease itself right at the source.

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



## Australian Expertise and Rapid Results

The HERACLES trial will take place in Australia to capitalise on Australian expertise in lupus research and early phase clinical trials. This will also help Noxopharm maximise rebates from the Australian Government's R&D Tax Incentive scheme.

HERACLES will be a high-potential, low-risk study focusing on safety and dose finding in healthy volunteers.

The trial has been designed to be easily implemented and rapid. 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 within six weeks after the readouts.

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