New Therapeutics for Autoimmune and Inflammatory Diseases

Proprietary Technologies to Reduce Inflammation

Noxopharm Ltd (ASX:NOX) is an innovative Australian biotech company discovering and developing novel drugs based on proprietary oligonucleotide technologies. Led by a highly experienced management team, its Sofra™ platform represents a pioneering approach to optimizing RNA vaccines and treating autoimmune and inflammatory diseases.

Blocking Inflammation at its Source

The Noxopharm Sofra™ technology platform is based on ultra-short oligonucleotides with diverse potential to improve RNA vaccines and therapeutics, as well as treat autoimmune diseases by mitigating inflammation.

Noxopharm and its subsidiary Pharmorage, in strategic collaboration with the Hudson Institute of Medical Research, have developed several preclinical 3-base oligonucleotides (3-mers) that have displayed highly potent and selective reduction of inflammation through binding to Toll-like receptors 7 and 8 (TLR7/8).

Abnormal TLR7 activity has long been implicated in the causation of systemic autoimmunity, and a recent study published in Nature has now definitively linked TLR7 with human lupus.[1]

The company is currently developing these oligonucleotides as a promising new class of therapeutics for autoimmune diseases such as lupus and psoriasis that involve overactivation of TLR7. Unlike most anti-inflammatory drugs that target the end-stages of the inflammatory process, Noxopharm's oligonucleotides act by blocking inflammation at its source.

SOF-SKN™ - A Novel Approach to Lupus

Noxopharm is addressing the autoimmune market with SOF-SKN™, its first Sofra drug candidate.

SOF-SKN is a topical treatment that contains a proprietary ultra-short oligonucleotide that is used to block TLR7, which is overactivated in lupus.

The drug has the potential to change the treatment paradigm of the skin disease caused by cutaneous lupus erythematosus (CLE) from merely controlling symptoms to actually treating the disease itself right at the source.

There are currently no approved therapeutic inhibitors of TLR7 on the market, making this a unique solution for an urgent unmet need.

The first in-human trial for SOF-SKN, known as HERACLES (for 'Harnessing Endogenous Regulators Against CLE Study'), will begin in 2025. It aims to provide initial safety and pharmacokinetic data, and will take place in Australia to capitalise on Australian expertise in lupus research and early phase clinical trials.

Estimates of the number of individuals suffering from autoimmune diseases in the US alone range from 14 to 24 million cases. The global immunology market is projected to grow from USD 92 billion in 2021 to USD 158 billion in 2028.

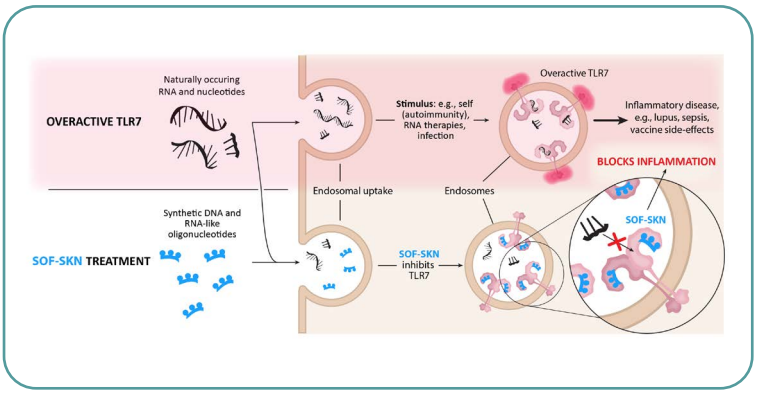

Figure 1. Representation of the effect of SOF-SKN on TLR7

Study Results

A recent challenge study demonstrated that topical application of Noxopharm's drug candidate SOF-SKN supresses inflammation and reduces disease in a mouse model of psoriasis-like inflammatory skin disease triggered by TLR7 activation.[2]

SOF-SKN was applied topically to the back and ear of mice once daily, followed immediately as a challenge by application of Aldara cream with active ingredient imiquimod to experimentally induce skin inflammation. Mice were scored daily for the appearance and severity of skin inflammation and, at the conclusion of the experiment, inflammatory gene signatures in the skin were analysed.

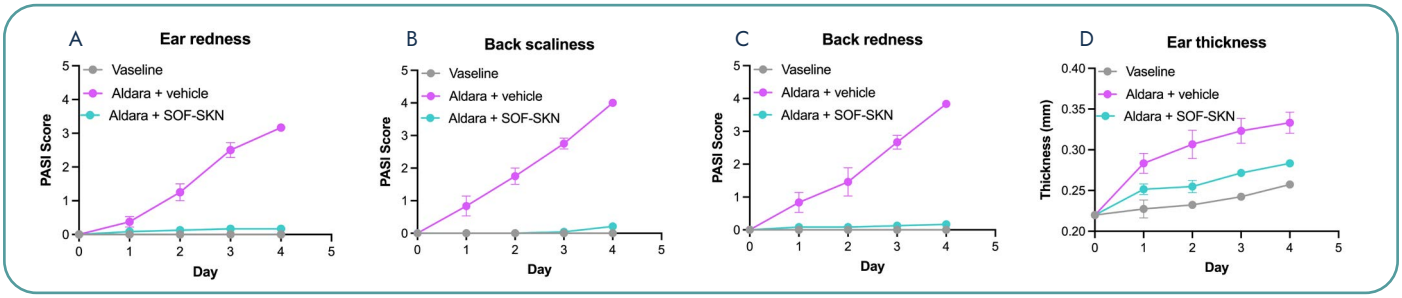

Figure 2. Scoring of inflammation in the Aldara-induced psoriasis model using the psoriasis area and severity index (PASI) ranging from 0 (normal) to 5 (marked, >50% total area). A) Ear redness; B) Back scaliness; C) Back redness; D) Ear thickness (mm)

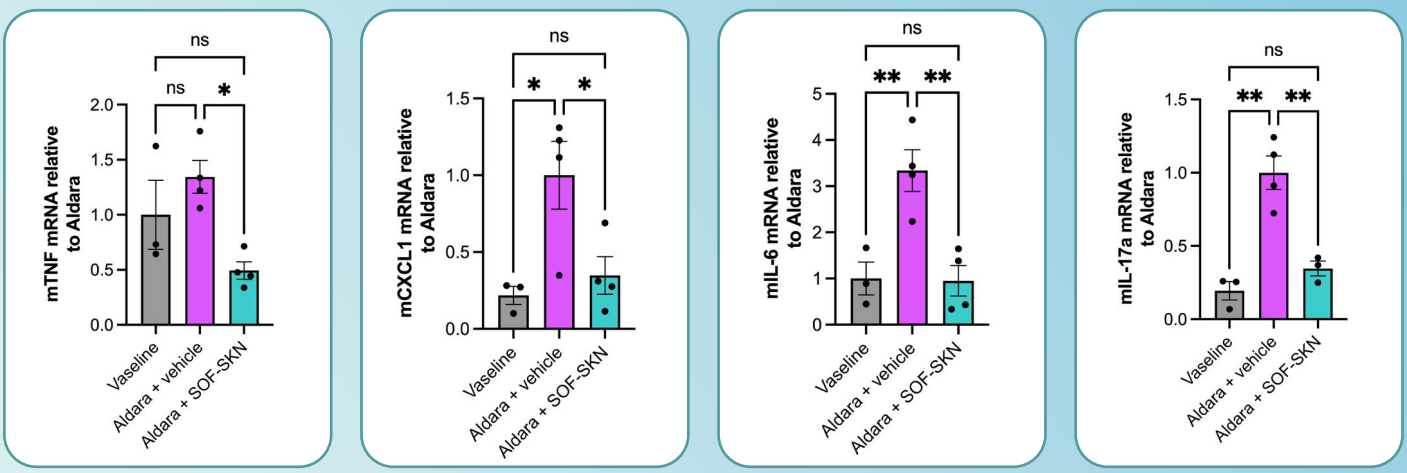

Figure 3. Analysis of inflammatory genes in the back skin of mice in the Aldara-induced skin inflammation model. * p<0.05, ** p<0.01, ns = not significant

SOF-SKN greatly reduced the severity of skin disease in a model of autoimmunity, reducing redness, scaling, and dermal thickening, and there was a significant reduction of inflammatory genes in the skin, indicating that TLR7 in the skin has been 'switched off'.

SOF-SKN has also successfully passed a standard set of IND-enabling studies demonstrating the safety of SOF-SKN with no geno-, cardio- or photo-toxicity.

SOF-SKN represents a promising new approach to the treatment of TLR7-driven inflammation.

REFERENCES

1. www.nature.com/articles/s41586-022-04642-z

2. lupus.bmj.com/content/10/Suppl_1/A37.3

SOF-SKN is not approved for use in Australia or any other country.

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