

Akaal Pharma has completed recruitment for a Phase-2 clinical trial for atopic dermatitis and associated pruritus

GREATER SHEPPARTON, VICTORIA, AUSTRALIA, June 5, 2024 /EINPresswire.com/ -- Akaal Pharma Pty Ltd has completed recruitment for a Phase-2 clinical trial involving patients with atopic dermatitis and associated pruritus.

Akaal Pharma Pty Limited (Akaal) today announced that it has completed recruitment of 140 patients for its Phase 2 clinical study to evaluate safety, tolerability and efficacy of topical 1% AKP-119 in atopic dermatitis participants with pruritus. The Phase 2 clinical study is a multicentre, randomized, double blind, placebo-controlled, two-arm study.

Akaal anticipates top-line data of the Phase 2 clinical study in Q3/4 of 2024. The Phase 2 clinical study targeted patients with atopic dermatitis patients that have mild to moderate disease with at least one lesion of moderate to severe pruritus.

This study follows a successful Phase-1a/1b clinical study Akaal completed on atopic dermatitis and psoriasis patients that showed AK-119 to be safe, well tolerated with clear signals of efficacy in relieving inflammation and disease score.

Atopic dermatitis is one form chronic skin inflammation where the associated pathology of pruritus largely impacts the patient's quality of life. Akaal's lead candidate, AK-119, is a broad action, differentiated S1P1 modulator able to downregulate multiple inflammatory, pain and pruritus factors with significant anti-inflammatory efficacy in the preclinical and in humans.

As well as topical applications, Akaal has been exploring the potential of AK-119 to be delivered orally. Akaal has completed a further Phase-1 clinical study in 40 healthy volunteers to evaluate the safety profile of AK-119 when administered orally. The results of the study showed no bradycardia/dyspnoea and mild lymphopenia (immune suppression), recovering to baseline within 24 hrs after multiple day dosing.

Akaal has shown its lead candidate, AK-119, has potential applications in several inflammatory/immune indications as well as an alternative for pain management. AK-119 has showed oral efficacy in animal models of neuropathic pain and the Phase-1 clinical study demonstrated safety and potentially targeting S1P1 area could have applications in neuropathic pain.

“At Akaal we continue to actively prioritize and expand our developmental programs to bring new and effective treatments into the market,” said co-CEO of Akaal Pharma Dr Antonio Rajic.

About Akaal Pharma Pty Ltd: Akaal Pharma is a private, clinical-stage, Australian biotechnology company focused on advancing its internally discovered topical and oral programs for the treatment of inflammatory/immune skin indications and pain indications. For more information, please visit www.akaalpharma.com

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