

Akaal Pharma Pty Ltd has received approval for a Phase-2 clinical trial involving patients with atopic dermatitis

AUSTRALIA, May 3, 2023 /EINPresswire.com/ -- Akaal Pharma Pty Ltd has received approval for a Phase-2 clinical trial involving patients with atopic dermatitis.

Akaal Pharma Pty Limited (Akaal) today announced that it has received regulatory approval from Drugs Controller General of India (DCGI) for a Phase-2 clinical study involving 150 participants to further evaluate the safety, tolerability, and efficacy of a topical formulation of AK-119 in atopic dermatitis participants with pruritus. AK-119 is a differentiated Spingosine-1-Phosphate receptor subtype-1 (S1P1) modulator. This study follows the successful Phase-1 study on atopic dermatitis and psoriasis patients that showed AK-119 to be safe, well tolerated with clear signals of efficacy relieving inflammation and disease score with non-significant systemic exposure via topical treatment. It is anticipated the Phase-2 clinical study will begin dosing patients in Q3 of 2023.

As well as topical applications, Akaal has been exploring the potential of AK-119 to be delivered orally. Akaal has completed a Phase-1 clinical study in 40 healthy volunteers to evaluate the safety profile AK-119 when administered orally. The study showed no bradycardia/dyspnoea and with mild lymphopenia (immune suppression), recovering to baseline within 24 hrs after multiple day dosing. The safety profile after systemic exposure via oral delivery is encouraging and we plan to explore other disease indications and expand to paediatrics.

AK-119 has potential applications in several inflammatory/ immune indications as well as an alternative for pain management. AK-119 showed efficacy in animal models of neuropathic pain and the Phase-1 safety findings support this novel S1P1 area for potential use 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 biotech 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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Bobby Sandhu

Akaal Pharma

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