Akaal Pharma Announces Positive Results from Phase 1 Clinical Study of Novel Topical AKP-11 for the Treatment of Psoriasis

Topical AKP-11 Meets Safety and Efficacy Endpoints

Phase 1 clinical trial results demonstrate AKP-11 to be safe, well-tolerated and effective topical treatment for mild to moderate psoriasis

MELBOURNE, Australia and SAN DIEGO, CA, USA, Jan 29, 2015. Akaal Pharma Pty Ltd, (Akaal Pharma), an Australian clinical-stage biopharmaceutical company focused on developing new small molecule drugs for the treatment of inflammatory and autoimmune diseases, today announced the positive results from a randomized, double-blind, placebo-controlled Phase-1 clinical trial of AKP-11, a novel and First-in-Class topical Sphingosine 1-Phosphate receptor-1 (S1P₁) modulator for the treatment of mild-to-moderate plaque psoriasis. In this study, the topical application of AKP-11 to psoriasis patients for 28 days was found to be safe, well tolerated and resulted in a significant reduction in plaque severity. No detectable plasma levels of AKP-11 were found in the pharmacokinetic analysis, which is attributable to the large therapeutic index of AKP-11.

“Although a variety of therapies are available for treating psoriasis, there exists an underserved need for safer and effective topical treatments for long-term use. The Phase 1 clinical data for AKP-11, a topical First-in-Class S1P₁ modulator, is very encouraging and strongly supports our Phase 2 clinical trial in a larger number of patients,” said Dale Dhanoa, Ph.D., CEO of Akaal Pharma.

Study Details

The Phase 1 clinical trial was a randomized, double-blind, and placebo-controlled study that involved 16 subjects. This study was conducted in 2 parts, Phase 1A and Phase 1B. AKP-11 or placebo were administered as an ointment to 4 healthy subjects in PART A and extended to 12 psoriasis patients in PART B. The patients were treated once daily with a topical application of AKP-11 for 28 consecutive days. AKP-11 reduced the local psoriasis severity index (LPSI) and demonstrated significant efficacy when compared to baseline (p=0.0016). The placebo group did not show efficacy. No clinically significant local or systemic adverse events were observed in the study.

About AKP-11

AKP-11 is a novel, potent and highly selective sphingosine 1-phosphate receptor subtype-1 (S1P₁) modulator undergoing clinical development for topical treatment of psoriasis and other skin diseases. AKP-11, a novel small molecule, has also shown excellent preclinical pharmacokinetic and pharmacodynamics profile as a potential Best-in-Class oral treatment for autoimmune indications. AKP-11 acts via multimodal actions and significantly reduces
the overexpression of pro-inflammatory cytokines and factors including the permeability factor VEGF.

About Psoriasis

Psoriasis is one of the most widespread autoimmune/inflammatory skin disorders affecting more than 2% of the global population, with no known cure. Psoriasis is a chronic disease that requires long-term treatment. Nearly 80% of patients have mild to moderate psoriasis. The disease is characterized by the presence of red, scaly patches known as psoriatic plaques, which are inflamed and produce excessive skin-cells. Psoriasis and other inflammatory skin disorders are characterized by marked infiltration of leukocytes into the dermis and epidermis, oedema, vascular leak, severe hyperplasia and inflammatory cytokine up-regulation. The current treatments suffer from known local and systemic side effects such as skin atrophy and others.

About Akaal

Akaal Pharma Pty Ltd (Akaal Pharma) is a clinical-stage drug discovery and development company focused on the development of novel small molecule drugs for the treatment of inflammatory and autoimmune diseases including psoriasis, atopic dermatitis, multiple sclerosis, ulcerative colitis, and rheumatoid arthritis. Akaal Pharma has created a robust pipeline of novel, potent, and highly selective S1P₁ receptor modulators that have shown an excellent oral and topical drug profile. Akaal Pharma applies its medicinal chemistry and drug discovery platform to discover and develop novel, safer and highly effective topical and oral drugs for the treatment of inflammation and immune diseases with unmet or undermet need. For more information, visit www.akaalpharma.com.

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Forward-Looking Statements

Certain statements in this new release concerning Akaal Pharma’s (Akaal Pharma Pty Ltd) business are considered “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, those relating to the timing and results of future clinical development of AKP-11, the expected safety, tolerability and potential efficacy of AKP-11 as compared to other drugs treating psoriasis and other skin and dermatological conditions. Any or all of the forward-looking statements in this press release can be affected by inaccurate assumptions Akaal Pharma might make or by known or unknown risks and uncertainties, including, but not limited to: the early stage of drug development; uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of drugs (products) under development. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Akaal Pharma Pty Ltd (Akaal Pharma) undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.