



NEWS RELEASE

Akaal Pharma Announces Superior Safety and Comparable Efficacy of Sphingosine 1-Phosphate Receptor-1 (S1P₁) Modulator AKP-11 as Compared to Gilenya (Fingolimod) for the Treatment of Multiple Sclerosis

Akaal Pharma's Oral Drug AKP-11 Exhibits Better Safety and Comparable Efficacy for Treatment of Multiple Sclerosis (MS) and other Autoimmune Diseases

MELBOURNE, Australia and SAN DIEGO, CA, USA, December 10, 2015. Akaal Pharma, a clinical-stage drug discovery and development company, today announced the publication of preclinical studies of safety and efficacy of its novel small molecule drug candidate AKP-11 in comparison with Gilenya (Fingolimod, FTY-720). Gilenya is a FDA approved oral drug for the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS). Multiple Sclerosis (MS) is a chronic inflammatory autoimmune disease of the central nervous system (CNS) that leads to demyelination with axonal damage and neuronal loss. MS is a debilitating disease afflicting nearly 2.5 million people worldwide.

In this study, efficacy and safety of our Sphingosine 1-phosphate receptor-1 (S1P₁) modulator AKP-11 was determined using in vitro cell culture and animal model Experimental Autoimmune Encephalomyelitis (EAE), a rat model for evaluating therapeutic efficacy of experimental drugs for the potential treatment of multiple sclerosis. Both treatments of EAE animals with AKP-11 or drug Gilenya provided similar efficacy and neuroprotection in the EAE model. AKP-11 treatment caused milder and reversible lymphopenia as compared to the severe and long lasting lymphopenia observed with Gilenya. The higher safety profile of AKP-11 on adverse effects (lymphopenia, heart rate and lung vasculature) as compared to Gilenya suggests AKP-11 as a potential safer drug. The study was conducted in Prof Inderjit Singh group at Charles P. Darby Children's Research Institute, Department of Pediatrics, Medical University of South Carolina, Charleston, South Carolina, USA. The full details of the study are described in the recent publication in the journal PLOS One; Samuvel et al. (2015) *AKP-11: A Novel S1P₁ Agonist with favorable safety profile attenuates experimental autoimmune encephalomyelitis in rat model of multiple sclerosis*. PLOS ONE 10(10): e0141781.doi:10.1371/journal.pone.0141781.

"The excellent drug profile of AKP-11 strongly supports its ongoing clinical development for the treatment of autoimmune and inflammatory diseases. AKP-11 is potentially a Best-in-Class oral drug for the treatment of multiple sclerosis, psoriasis, ulcerative colitis and other autoimmune and inflammatory diseases, said Dale Dhanoa, Ph.D., CEO of Akaal Pharma.

AKP-11

AKP-11 is a next generation of potent and highly selective Sphingosine-1-Phosphate receptor-1 (S1P₁) modulator with excellent drug profile including oral bioavailability, short half-life, high volume of distribution and clearance. AKP-11 shows no hERG ion channel blocker activity even at high concentration of 30µM. AKP-11 is a highly metabolically stable drug candidate that eliminates

potential adverse events associated with metabolites and S1P₁ receptor degradation. AKP-11 is a potential Best-in-Class oral drug that is ready for initiating a Phase I clinical trial for the treatment of multiple sclerosis and other autoimmune diseases.

The S1P₁ modulator AKP-11 acts via multimodal actions by attenuating overexpression of pro-inflammatory cytokines and factors including vascular permeability factor supporting its wide ranging topical use for treating dermatological disorders. AKP-11 has shown significant advantage as a topical agent for the treatment of mild-to-moderate psoriasis in Phase 1 clinical trials and it is initiating dosing both in Phase II clinical trials for psoriasis and Phase I/II for atopic dermatitis in January 2016.

About Akaal

Akaal Pharma Pty Ltd is a clinical-stage drug discovery and development company focused on advancing its new small molecule drugs for the treatment of inflammation and autoimmune diseases including psoriasis, atopic dermatitis, multiple sclerosis, ulcerative colitis and others. For more information, please visit www.akaalpharma.com.

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