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Zydus Lifesciences initiates Ph II clinical trial for treatment of Amyotrophic Lateral Sclerosis

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Phase 2 clinical trial will assess the safety and efficacy of ZYIL1 in Amyotrophic Lateral Sclerosis (ALS) patients

Ahmedabad-based company Zydus Lifesciences has received permission from the Central Drugs Standard Control Organisation (CDSCO), Government of India, to initiate the Phase II clinical study of NLRP3 inhibitor “ZYIL1” in patients with Amyotrophic Lateral Sclerosis (ALS).

Pankaj R. Patel, Chairman, Zydus Lifesciences said, “By targeting neuroinflammation and neurodegeneration with ZYIL1, we hope to open up new possibilities in treating ALS.”

ALS patients experience neuroinflammation and rapid neurodegeneration leading to steady loss of the ability to move, speak, eat and eventually breathe. ALS results in loss of motor neurons in the brain and spinal cord which controls voluntary muscle movement.

The Phase II clinical trial will study safety, tolerability, pharmacokinetics and pharmacodynamics in patients with ALS. The change from baseline in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) score will be measured at week 4, week 8 and week 12, as the trial’s primary endpoint is the placebo-controlled, randomised, double-blind Phase 2 clinical trial. The trial will also evaluate Key Secondary Endpoints including Slow Vital Capacity (SVC), a predictor of functional loss in ALS and neurofilament levels at week 4 and week 12.

ZYIL1 is a novel oral small molecule NLRP3 inhibitor. Studies have demonstrated that ZYIL1 is highly potent in human whole blood assay and can suppress inflammation caused by the NLRP3 inflammasome. ZYIL1 was found distributed in the brain and CSF of various nonclinical species including mice, rats and non-human primates. The efficacy of ZYIL1 has been established in several validated pre-clinical models of neuroinflammation, Parkinson’s disease, Inflammatory Bowel Disease (IBD) and Multiple Sclerosis (MS).