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Australia's Alterity Therapeutics to start phase 2 trial of neuro drug in UK

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Alterity Therapeutics announces regulatory authorization to proceed with ATH434 phase 2 clinical trial in the United Kingdom

Alterity Therapeutics, a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, announced that the United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA) has accepted Alterity's clinical trial authorisation (CTA) request to conduct its Phase 2 clinical trial for ATH434 in Multiple System Atrophy (MSA), a rare and highly debilitating Parkinsonian disorder.

"Approval by the MHRA in the UK is another important step forward for our ATH434 clinical development program," said David Stamler, M.D., Chief Executive Officer, Alterity. "We expect to open our first Phase 2 clinical trial site in New Zealand this quarter and then expand the trial globally in the UK, other European countries, Australia and the United States. We look forward to bringing this potential therapy to individuals with MSA who currently have no treatments to address the underlying pathology of their disease."

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage MSA. The study will explore the effect of ATH434 treatment on imaging and protein biomarkers such as aggregating ?-synuclein and excess iron, which are important contributors to MSA pathology. Clinical endpoints and other biomarkers will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. Patients will receive treatment for 12 months which will provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive Phase 3 study.