https://alteritytherapeutics.com/investor-centre/news/2022/07/06/alterity-therapeutics-doses-first-patient-in-ath434-phase-2-clinical-trial-in-multiple-system-atrophy/

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Alterity Therapeutics traite le premier patient de l'essai clinique de phase 2 ATH434 sur l'atrophie multi-systématisée

6 juillet 2022 Alterity Therapeutics

Alterity Therapeutics (ASX : ATH, NASDAQ : ATHE) (« Alterity » ou « l'entreprise »), une société de biotechnologie dédiée au développement de traitements modificateurs de la maladie pour les maladies neurodégénératives, a annoncé aujourd'hui que le premier patient a reçu une dose dans l'essai clinique de phase 2 de l'entreprise de l'ATH434 dans l'atrophie multi-systématisée (AMS), une maladie parkinsonienne rare et très invalidante.

Bien qu'elle ressemble à la maladie de Parkinson, l'AMS progresse plus rapidement et entraîne une invalidité profonde. En plus des symptômes moteurs caractéristiques de la maladie de Parkinson, l'AMS se manifeste par une altération plus sévère du système nerveux autonome entraînant un dysfonctionnement de la vessie et l'incapacité à maintenir une tension artérielle normale, ainsi que des mouvements non coordonnés ou maladroits qui contribuent à la chute. Il n'y a pas de causes connues ou de facteurs de risque spécifiques associés à la maladie.

« Le dosage de notre premier patient est une étape importante pour Alterity alors que nous cherchons à apporter une nouvelle option de traitement potentielle aux personnes atteintes d'AMS », a déclaré David Stamler, M.D., directeur général d'Alterity. *"Ce n'est que la première étape, car nous prévoyons d'augmenter les inscriptions dans plusieurs régions au cours du second semestre de cette année. Nous sommes reconnaissants à toute l'équipe clinique du New Zealand Brain Research Institute dont l'efficacité et le dévouement envers leurs patients ont soutenu cette réalisation. »*

« En tant que clinicien qui s'occupe de personnes atteintes d'AMS, je suis très heureux qu'Alterity ait choisi d'amener cet essai clinique d'une nouvelle thérapie prospective en Nouvelle-Zélande. Il n'existe actuellement aucun traitement disponible pour ralentir ou empêcher la progression de ce trouble cérébral pénible, de sorte que des essais comme celui-ci sont les bienvenus », a ajouté le professeur Tim Anderson, chercheur principal de l'essai au New Zealand Brain Research Institute.

L'essai clinique de phase 2 est une étude randomisée, en double aveugle et contrôlée par placebo sur l'ATH434 chez des patients atteints d'AMS à un stade précoce. **L'étude explorera l'effet du traitement ATH434 sur l'imagerie et les biomarqueurs protéiques, tels que l'agrégation de l'α-synucléine et l'excès de fer,** qui sont des contributeurs importants à la pathologie AMS. Les paramètres cliniques et les biomarqueurs permettront une évaluation complète de l'efficacité de l'ATH434 ainsi que la caractérisation de l'innocuité et de la pharmacocinétique. **L'étude devrait recruter environ 60 patients adultes** qui recevront l'une des deux doses d'ATH434 ou un placebo. Les patients recevront un traitement **pendant 12 mois**, ce qui permettra de détecter des changements dans les paramètres d'efficacité afin

d'optimiser la conception d'une étude définitive de phase 3. Des informations supplémentaires sur l'essai de phase 2 peuvent être trouvées sur : ClinicalTrials.gov Identifier: NCT05109091.

Alterity Therapeutics Doses First Patient in ATH434 Phase 2 Clinical Trial in Multiple System Atrophy

July 6, 2022 Alterity Therapeutics

Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced the first patient has been dosed in the Company's Phase 2 clinical trial of ATH434 in Multiple System Atrophy (MSA), a rare and highly debilitating Parkinsonian disorder.

While it is similar to Parkinson's disease, MSA progresses more rapidly and causes profound disability. In addition to the motor symptoms characteristic of Parkinson's disease, MSA manifests with more severe autonomic nervous system impairment resulting in bladder dysfunction and the inability to maintain normal blood pressure, as well as uncoordinated or clumsy movements that contribute to falling. There are no known causes or specific risk factors associated with the disease.

"Dosing of our first patient is a significant milestone for Alterity as we look to bring a potential new treatment option to individuals living with MSA," said David Stamler, M.D., Chief Executive Officer, Alterity. "This is just the first step as we expect to expand enrolment in multiple regions over the second half of this year. We are grateful to the entire clinical team at the New Zealand Brain Research Institute whose efficiency and dedication to their patients supported this accomplishment."

"As a clinician looking after people with MSA, I'm very pleased that Alterity has chosen to bring this clinical trial of a novel prospective therapy to New Zealand. There is presently no available treatment to slow down or prevent progression of this distressing brain disorder so trials such as this are very welcome," added Professor Tim Anderson, Lead Investigator of the trial at the New Zealand Brain Research Institute.

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 α-synuclein and excess iron, which are important contributors to MSA pathology. Clinical and biomarker endpoints will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. The study is expected to enroll approximately 60 adult patients to receive one of two doses of ATH434 or placebo. 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. Additional information on the Phase 2 trial can be found by ClinicalTrials.gov Identifier: NCT05109091.

About ATH434

Alterity's lead candidate, ATH434, is the first of a new generation of small molecules designed to inhibit the aggregation of pathological proteins implicated in neurodegeneration. ATH434 has been shown preclinically to reduce α-synuclein pathology and preserve nerve cells by restoring normal iron balance in the brain. In this way, it has excellent potential to treat Parkinson's disease as well as various forms of atypical Parkinsonism such as Multiple System Atrophy (MSA). ATH434 has successfully completed a Phase 1 clinical trial demonstrating the agent is well tolerated, orally bioavailable, and achieved brain levels comparable to efficacious levels in animal models of MSA, with the objective of restoring function in patients with MSA and other Parkinsonian disorders.

ATH434 has been granted Orphan designation for the treatment of MSA by the U.S. FDA and the European Commission.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease characterized by failure of the autonomic nervous system and impaired movement. The symptoms reflect the progressive loss of function and death of different types of nerve cells in the brain and spinal cord. It is a rapidly progressive disease and causes profound disability. MSA is a Parkinsonian disorder characterized by a variable combination of slowed movement and/or rigidity, autonomic instability that affects involuntary functions such as blood pressure maintenance and bladder control, and impaired balance and/or coordination that predisposes to falls. A pathological hallmark of MSA is the accumulation of the protein α-synuclein within glia, the support cells of the central nervous system, and neuron loss in multiple brain regions. MSA affects approximately 15,000 individuals in the U.S., and while some of the symptoms of MSA can be treated with medications, currently there are no drugs that are able to slow disease progression and there is no cure.[1]

[1]National Institute of Health: Neurological Disorders and Stroke, Multiple System Atrophy Fact Sheet

About Alterity Therapeutics Limited

Alterity Therapeutics is a clinical stage biotechnology company dedicated to creating an alternate future for people living with neurodegenerative diseases. The Company's lead asset, ATH434, has the potential to treat various Parkinsonian disorders. Alterity also has a broad drug discovery platform generating patentable chemical compounds to intercede in disease processes. The Company is based in Melbourne, Australia, and San Francisco, California, USA. For further information please visit the Company's web site at www.alteritytherapeutics.com.