



## **Alterity Therapeutics Phase 2 Data Monitoring Committee Recommends Continuing Clinical Trial as Planned After Third Review**

*- ATH434-201 Trial on Track to Complete in November 2024 –*

*- Top-Line Data Expected in January 2025 -*

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 8 May 2024:** Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) (“Alterity” or “the Company”), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced that an independent Data Monitoring Committee (DMC) has completed its third review of trial data and recommended the ATH434-201 Phase 2 study continue as planned. The ATH434-201 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage multiple system atrophy (MSA), a rare neurodegenerative disease with no approved treatments to slow or stop its progression.

The DMC conducted its prespecified review of unblinded clinical data from study participants. The DMC expressed no concerns about safety and recommended that the study continue without modification. The plan for the DMC to review clinical data from the trial has been cleared with the U.S. Food and Drug Administration.

“We are pleased to report that the Data Monitoring Committee for our ATH434-201 Phase 2 clinical trial has again determined that there are no safety concerns and that the study can continue as planned,” said David Stamler, M.D., Chief Executive Officer of Alterity. “This recommendation is important as ATH434 continues to demonstrate a favorable safety profile with long term exposure. The trial remains on track to complete in November 2024 and report top-line data in January 2025.”

The ATH434-201 Phase 2 clinical trial is evaluating the effect of ATH434 treatment on neuroimaging and protein biomarkers to demonstrate target engagement and clinical endpoints to demonstrate efficacy, in addition to assessments of safety and pharmacokinetics. Selected biomarkers, such as brain iron and aggregating  $\alpha$ -synuclein, are important contributors to MSA pathology and are therefore appropriate targets to demonstrate drug activity. Wearable sensors have also been employed to evaluate motor activities that are important to patients with MSA. The study enrolled 77 adults who were randomly assigned to receive one of two dose levels of ATH434 or placebo. Participants 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 an oral agent designed to inhibit the aggregation of pathological proteins implicated in neurodegeneration. ATH434 has been shown preclinically to reduce  $\alpha$ -synuclein pathology and preserve neuronal function by restoring normal iron balance in the brain. As an iron chaperone, it has excellent potential to treat Parkinson's disease as well as various Parkinsonian disorders such as Multiple System Atrophy (MSA). ATH434 successfully completed Phase 1 studies demonstrating the agent is well tolerated and achieved brain levels comparable to efficacious levels in animal models of MSA. ATH434 is currently being studied in two clinical trials: Study ATH434-201 is a randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with early-stage MSA and Study ATH434-202 is an open-label Phase 2 Biomarker trial in patients with more advanced MSA. ATH434 has been granted Orphan drug 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  $\alpha$ -synuclein within glia, the support cells of the central nervous system, and neuron loss in multiple brain regions. MSA affects at least 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.<sup>1</sup>

<sup>1</sup>[Multiple System Atrophy | National Institute of Neurological Disorders and Stroke \(nih.gov\)](#)

### **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](http://www.alteritytherapeutics.com).

## **Authorisation & Additional information**

This announcement was authorized by David Stamler, CEO of Alterity Therapeutics Limited.

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## **Forward Looking Statements**

*This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements.*

*Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are described in the sections titled "Risk Factors" in the Company's filings with the SEC, including its most recent Annual Report on Form 20-F as well as reports on Form 6-K, including, but not limited to the following: statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, ATH434, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, ATH434, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, ATH434, that could slow or prevent products coming to market, the uncertainty of obtaining patent protection for the Company's intellectual property or trade secrets, the uncertainty of successfully enforcing the Company's patent rights and the uncertainty of the Company freedom to operate.*

*Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no*

*obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.*