



## **Alterity Therapeutics Completes Last Patient Visit in ATH434-202 Open-Label Phase 2 Trial in Multiple System Atrophy**

*– ATH434 is a Disease Modifying Drug Candidate Targeting Parkinsonian Disorders –*

*– Topline Data Expected Mid-Year 2025 –*

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 27 March 2025:** 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 the last patient in the ATH434-202 Phase 2 trial has completed the study. The ATH434-202 is an open label study designed to evaluate the safety, efficacy and target engagement of ATH434 in participants with advanced multiple system atrophy (MSA).

“Following the positive results from our randomized, double-blind Phase 2 trial<sup>1</sup>, we are pleased to announce that the last participant has now completed all clinical evaluations in our open-label study of advanced MSA,” said, David Stamler, M.D., Chief Executive Officer of Alterity. “The 202 study gives us the opportunity to evaluate the effects of ATH434 treatment in a population that faces severe challenges due to the stage of their illness. The data from this study will help guide our development program given the differences between the 202 study and the double-blind trial. I greatly appreciate the contributions of the trial participants and thank them for their participation. We look forward to reporting topline data from this study in mid-year 2025.”

### **About ATH434-202 Phase 2 Clinical Trial**

The ATH434-202 Phase 2 clinical trial is an open label study, entitled “A Biomarker Study of ATH434 in Participants with MSA.” The Biomarker trial enrolled 10 individuals with advanced MSA. ATH434-202 study participants received treatment with ATH434 at the 75 mg dose for 12-months. The study will assess the effect of ATH434 treatment on neuroimaging and protein biomarkers to evaluate target engagement, in addition to clinical measures, safety, and pharmacokinetics. The selected biomarkers, including brain volume, iron and aggregating  $\alpha$ -synuclein, are important contributors to MSA pathology and are appropriate targets to demonstrate drug activity. The primary objective of this study is to evaluate the impact of 12 months treatment with ATH434 on brain volume in a more advanced patient population than was studied in Alterity’s randomized Phase 2 trial. Additional information on the open label Phase 2 trial can be found at [clinicaltrials.gov NCT05864365](https://clinicaltrials.gov/NCT05864365).

## 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 recently announced positive results from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with early-stage MSA. A second Phase 2 open-label 2 Biomarker trial in patients with more advanced MSA is ongoing. 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 \(nih.gov\)](https://www.ninds.nih.gov/Disorders/PalliativeCare/multiple-system-atrophy)

## 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 is initially focused on developing disease modifying therapies in Parkinson's disease and related disorders. Alterity recently reported positive data for its lead asset, ATH434, in a Phase 2 clinical trial in participants with Multiple System Atrophy (MSA), a rare and rapidly progressive Parkinsonian disorder. ATH434 is also being evaluated in a Phase 2 clinical trial in advanced MSA. In addition, Alterity has a broad drug discovery platform generating patentable chemical compounds to treat the underlying pathology of neurological diseases. The Company is based in Melbourne, Australia, and San Francisco, California, USA. For further information please visit the Company's website at [www.alteritytherapeutics.com](http://www.alteritytherapeutics.com).

**Sources:**

<sup>1</sup>ATH434-201 Phase 2 trial results [release](#)

**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.*