

# Alterity Therapeutics to Deliver an Oral Presentation of the Positive ATH434 Phase 2 Trial Results at the American Academy of Neurology Annual Meeting

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 3 April 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 an oral presentation and a poster presentation related to Alterity's clinical programs in Multiple System Atrophy (MSA) will be delivered at the American Academy of Neurology (AAN) 2025 Annual Meeting taking place April 5 - 9, 2025 in San Diego, CA.

David Stamler, M.D., Chief Executive Officer of Alterity, commented, "We are excited to present the positive topline data along with new analyses from our ATH434-201 clinical trial via an oral presentation at AAN, one of the premier global neurology meetings. In addition, data will be presented on the use of wearable sensor technology to assess patient outcomes, an important component of evaluating novel treatments for individuals with MSA."

Type: Oral Presentation

Title: Topline Data from a Randomized, Double Blind, Placebo Controlled Phase 2

Study of ATH434 in Multiple System Atrophy

Presenter: Daniel Claassen, M.D., M.S., Professor of Neurology at Vanderbilt University

**Medical Center** 

Date/Time: Wednesday, April 9, 2025 at 2:24 PM PDT (USA)

Type: Poster Presentation

Title: Association Between Wearable Sensor Data and Clinical Scores in Individuals

with Early-stage Multiple System Atrophy

Presenter: Ashkan Vaziri, PhD, BioSensics LLC

Date/Time: Saturday, April 5, 2025 at 11:45 AM PDT (USA)

## **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 ATH434-201 Phase 2 Clinical Trial

The ATH434-201 Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of 12 months treatment with ATH434 in patients with MSA. The study evaluated the efficacy, safety and pharmacokinetics of ATH434 as well as the effect of ATH434 on neuroimaging and protein biomarkers. Wearable sensors were employed to evaluate motor activities outside of the clinic. The study enrolled 77 adults who were randomly assigned to receive ATH434 50 mg or 75 mg twice daily or matching placebo. The topline data showed that ATH434 produced clinically and statistically significant improvement on the modified UMSARS Part I, a functional rating scale that assesses disability on activities of daily living affected in MSA. In addition to the robust efficacy demonstrated on the UMSARS Part I, trends in improved motor performance were observed on the Parkinson's Plus rating scale and overall benefit was shown on the Clinical Global Impression of Severity at the 50 mg dose. Wearable sensor data indicated that both dose levels of ATH434 led to increased activity in an outpatient setting as compared to placebo. Biomarkers were used to evaluate potential drug effect and target engagement. Both dose levels reduced iron accumulation in MSA affected brain regions and trends in preservation of brain volume were observed relative to placebo. Additional information on the Phase 2 trial can be found by ClinicalTrials.gov Identifier: NCT05109091.

## **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.  $\alpha$ 

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

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.

#### **Authorisation & Additional information**

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

## **Investor and Media Contacts:**

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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.