



Alterity Therapeutics Data Presentations Support Advancement of ATH434 into Phase 3 in Multiple System Atrophy

– Alterity’s novel imaging and biomarker approach positions the Company at the forefront of clinical research in MSA –

– End-of-Phase 2 FDA Meeting on track for mid-2026 to confirm path forward for Phase 3 –

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 19 May 2026: [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 presentations related to the Company’s development program in Multiple System Atrophy (MSA) were delivered at three medical conferences showcasing Alterity’s novel imaging and biomarker approach, promising Phase 2 data, and current plans to advance ATH434 into Phase 3 clinical development.

“These data continue to strengthen the evidence that ATH434 has the potential to be the first disease-modifying treatment for MSA, a rare and devastating disease with no approved therapy,” said David Stamler, M.D., CEO of Alterity Therapeutics. “Our Phase 2 trial showed statistically significant slowing of disease progression, and the use of advanced MRI methods gives us a powerful way to identify the right patients and measure how the drug is working. Together, these advances directly inform the design of our upcoming Phase 3 trial. By moving beyond traditional trial paradigms, we are focused on identifying and treating the right patients with greater precision, with the ultimate goal of delivering a meaningful therapeutic option for this devastating disease.”

Presentation Highlights:

Quantitative Susceptibility Mapping Detects Progressive Iron Accumulation in Early MSA

- Author: Oral presentation delivered by Paula Trujillo, PhD, Research Assistant Professor, Department of Neurology, Vanderbilt University Medical Center
- Conference: The International Society for Magnetic Resonance in Medicine 2026 ISMRM and ISMRT Annual Meeting and Exhibition
- Summary: New research shows that Alterity’s MRI imaging approach can detect MSA in its earliest stages and track brain iron changes over time, a methodology that could transform how MSA trials are run. Dr. Trujillo presented findings recently published in *NeuroImage* demonstrating that quantitative susceptibility mapping (QSM) detects progressive iron

accumulation in MSA. The measure may serve as a biomarker for early diagnosis, monitoring, and trial enrichment. The evaluation utilizes longitudinal data generated through Alterity's Biomarkers of Progression in Multiple System Atrophy (bioMUSE) Natural History Study, together with additional cross-sectional MSA, Parkinson's Disease, and healthy control data. QSM provides the ability to: detect iron dysregulation early — even before clinical diagnosis, track progression over 12 months, provide individual-level, interpretable maps for monitoring, and it is standardizable across scanners which can provide a meaningful tool for multicenter trials.

Results from a Randomized, Double-Blind, Placebo-Controlled Study of ATH434 in MSA using CSF NfL as a Covariate

- Author: Poster presentation delivered by Daniel Claassen, M.D., M.S., Professor of Neurology at Vanderbilt University Medical Center and Chief Medical Advisor for Alterity
- Conference: Movement Disorder Society of Australia and New Zealand (MDSANZ) Scientific Meeting
- Summary: A new analysis of Alterity's Phase 2 trial brings together clinical, biomarker, and imaging evidence that support ATH434's impact on slowing MSA progression. Dr. Claassen's poster described outcomes from the ATH434-201 Phase 2 clinical trial in MSA. In particular, the poster evaluates CSF NfL¹ which is an established prognostic biomarker of clinical decline in MSA and was prespecified as a disease-severity covariate in the trial. There were several key outcomes:
 - 1) ATH434 slowed functional decline in MSA: Significant effect at 50 mg BID (−4.0 points, $p=0.035$; ~48% slowing) and a consistent directional trend at 75 mg BID. Combined active arms significantly slowed UMSARS² I progression vs placebo ($p=0.047$).
 - 2) CSF NfL is a meaningful prognostic covariate: Higher baseline CSF NfL predicted greater UMSARS-I worsening ($\beta=0.90$, $p=0.033$). Adjusting for it strengthened detection of treatment effects and supports CSF NfL for stratification in future trials.
 - 3) Imaging supports the iron-chaperone mechanism: QSM trend of reduced iron accumulation in putamen and globus pallidus consistent with the iron-chaperone mechanism of action; the dentate signal increase is consistent with glymphatic iron redistribution rather than disease progression.
 - 4) ATH434 is a promising potential disease-modifying therapy: Convergent clinical, biomarker, and imaging signals support continued development.

ATH434 Clinical Update and Phase 3 Planning

- Author: Oral presentation delivered by David Stampler, M.D., CEO of Alterity Therapeutics
- Conference: MSA Symposium (University College London) 2026
- Summary: New analyses of Alterity's Phase 2 trial were presented, bringing together clinical, biomarker, and imaging evidence that support ATH434's impact on slowing MSA progression. In particular, analyses of key clinical endpoints, including the Unified MSA rating scale Part I, were presented that include CSF NfL as a covariate. The biomarker data presented by Dr.

Stamler included QSM MRI data from the ATH434-201, demonstrating that ATH434 decouples iron accumulation from clinical progression thus supporting its role as an iron chaperone. New data on the impact of ATH434 on swallowing were also presented, demonstrating that both doses of ATH434 reduce the progression of this key MSA symptom. Swallowing impairment was assessed with the 15-item Swallowing Disturbance Questionnaire (SDQ), a validated patient reported outcome. Over 52 weeks treatment, placebo patients worsened by a mean adjusted increase score of 8.5 points as compared to an increase of 1.2 and 5.0 points for the 50 mg and 75 mg groups, respectively, with the mean adjusted difference at 50 mg achieving statistical significance ($p=0.003$).

The presentations are available on the Alterity Therapeutics website [here](#).

About ATH434

Alterity's lead candidate, ATH434, is an oral agent designed to reduce iron accumulation and inhibit abnormal protein aggregation associated with neurodegeneration. ATH434 has been shown to reduce α -synuclein pathology and preserve neuronal function by restoring normal iron balance in the brain in preclinical models. 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). Positive results from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with MSA demonstrated robust clinical efficacy, target engagement as indicated by key biomarkers, and a favorable safety profile. Positive data from a second Phase 2 open-label biomarker trial in patients with more advanced MSA reinforced these results. ATH434 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), and Orphan Drug Designation by the FDA and the European Commission for the treatment of MSA.

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 data showed that, compared to placebo, ATH434 produced clinically and statistically significant improvement on the modified Unified Multiple System Atrophy Rating Scale (UMSARS) Part I, a functional rating scale that assesses disability on activities of daily living affected in MSA. Additional efficacy assessments demonstrated improvement consistent with the positive UMSARS Part I findings including trends in improved motor performance on the Parkinson's Plus rating scale, the Clinical Global Impression of Severity Scale, and the Orthostatic Hypotension Symptom Assessment (a patient reported outcome). Wearable sensor data indicated that ATH434 also led to increased

activity in an outpatient setting. Biomarkers were used to evaluate potential drug effect and target engagement relative to placebo. Both dose levels reduced iron accumulation in MSA affected brain regions with trends in preservation of brain volume. ATH434 was well tolerated with similar adverse event rates compared to placebo and no serious adverse events attributed to ATH434. Additional information on the Phase 2 trial can be found by [ClinicalTrials.gov Identifier: NCT05109091](https://clinicaltrials.gov/ct2/show/study/NCT05109091).

About bioMUSE

Biomarkers of progression in Multiple System Atrophy (bioMUSE) is a natural history study that aims to track the progression of individuals with MSA, a parkinsonian disorder without an approved therapy. The study is being conducted in collaboration with Vanderbilt University Medical Center in the U.S. under the direction of Daniel Claassen, M.D., M.S., Professor of Neurology and Principal Investigator. Natural history studies are important for characterizing disease progression in selected patient populations. The study has provided rich data for optimizing the design of Alterity's randomized ATH434-201 Phase 2 clinical trial and enrolled approximately 20 individuals with clinically probable or clinically established MSA. BioMUSE continues to provide vital information on early stage MSA patients, informs the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy, and delivers clinical data to characterize disease progression in a patient population that mirrors those currently enrolling in the Phase 2 clinical trial.

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 up to 50,000 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.³

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 focused on developing disease modifying therapies in Multiple System Atrophy (MSA) and related Parkinsonian disorders. Alterity is preparing to initiate a Phase 3 pivotal trial in MSA, a rare and rapidly

progressive disease. ATH434, the Company's lead asset, has demonstrated clinically meaningful efficacy in a randomized, double-blind, placebo-controlled Phase 2 clinical trial in participants with MSA. Alterity has further reported positive data in its open label Phase 2 clinical trial in participants with 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 <https://alteritytx.com>.

References:

¹ Neurofilament Light Chain measured in the cerebrospinal fluid (CSF)

² UMSARS: Unified Multiple System Atrophy Rating Scale, Parts I & II

³ [Multiple System Atrophy | National Institute of Neurological Disorders and Stroke \(nih.gov\)](#)

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.