Alterity Therapeutics Granted U.S. FDA Fast Track Designation for ATH434 to Treat Multiple System Atrophy

– Fast Track Designation highlights potential of ATH434 to address high unmet need for individuals with MSA –

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 5 May 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ATH434 for the treatment of Multiple System Atrophy (MSA). This designation is intended to accelerate the development and review of novel investigational products such as ATH434 and recognizes its potential as an innovative approach to address the high unmet need for treating MSA, a disease with no approved therapy.

"Receiving the FDA's Fast Track Designation for ATH434, alongside the Orphan Drug Designation we have already received, underscores the promise of this novel agent to address the urgent need for a disease modifying therapy for individuals with MSA," said, David Stamler, M.D., Chief Executive Officer of Alterity. "This designation reinforces the potential of ATH434 as demonstrated by recent scientific findings related to its mechanism of action and the robust and clinically meaningful efficacy from our double-blind Phase 2 clinical trial. Importantly, the Fast Track designation provides us the opportunity to interact with the FDA more frequently on the advancement of ATH434, potentially accelerating its development path and approval. We look forward to leveraging the Fast Track designation to bring this promising treatment to patients as quickly as possible."

About FDA Fast Track Designation

The Fast Track Designation is intended to facilitate and expedite the development and review of new drugs for serious conditions with unmet medical needs, such as MSA. Fast Track designation for a drug candidate confers some or all of the following benefits:

- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Opportunities for more frequent and early communication with the FDA throughout the development process
- Rolling review for the future New Drug Application (NDA) that allows the FDA to begin reviewing sections of an application as they are completed, rather than waiting for the full application.

Fast Track eligibility requires demonstration of the potential for clinically meaningful benefits, which can include the mechanism of action, preclinical studies, or data from patient studies. Alterity's previous interactions with the FDA indicated that the modified Unified Multiple System Atrophy Rating Scale (UMSARS) Part I scale is considered a clinically meaningful endpoint for MSA. Alterity's Fast Track application included top-line data from the ATH434-201 randomized, double-blind Phase 2 clinical trial which demonstrated efficacy on the modified UMSARS I in addition to preclinical data confirming that ATH434 is a low to moderate affinity iron chaperone.

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 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). Phase 1 studies have demonstrated the agent is well tolerated and achieved brain levels comparable to efficacious levels in animal models of MSA. Positive results from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with MSA demonstrated robust clinical efficacy, target engagement on key biomarkers, and a favorable safety profile. A second Phase 2 open-label biomarker trial in patients with more advanced MSA is ongoing. ATH434 has been granted Fast Track Designation by the U.S. FDA, and Orphan Drug Designation by the U.S. 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 stabilized or 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.

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 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.[1]

[1]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 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.

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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.