Alterity Therapeutics Initiates Second Phase 2 Study in Rare Parkinsonian Disorder

- ATH434 now being evaluated in early and more advanced Multiple System Atrophy -

- New trial expected to generate data before ongoing Phase 2 trial -

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 30 May 2023: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced it has commenced a new Phase 2 clinical trial of ATH434 in patients with Multiple System Atrophy (MSA) and the first patient has been enrolled. This open label study, entitled "A Biomarker Study of ATH434 in Participants with MSA" (ATH434-202) is in addition to the ongoing, randomized, double-blind, placebo-controlled Phase 2 trial in early-stage MSA (ATH434-201).

The Biomarker trial will enroll approximately 15 individuals with more advanced MSA than those participating in the randomized trial. A key aim of the study is to assess the efficacy of ATH434 on objective biomarkers that measure target engagement and are relevant to the underlying pathology of disease. Clinical measures important in MSA will also be assessed.

"This Phase 2 Biomarker study complements our ongoing randomized Phase 2 trial, allowing us to evaluate the effect of ATH434 on two MSA populations of differing severity," said David Stamler, M.D., Chief Executive Officer, Alterity. "Individuals with more advanced MSA may also benefit from ATH434 and measuring key biomarkers will permit us to evaluate drug activity in this population. The data derived from these two trials will help us optimize and potentially accelerate future development."

"Importantly, the randomized Phase 2 trial is proceeding as planned, but the design of this new study will allow us to perform interim analyses of biomarker data during conduct, which could give us early indications of efficacy. We expect to have preliminary data from an initial cohort of enrolled participants before the randomized study reads out," added Dr. Stamler.

ATH434-202 study participants will receive treatment with ATH434 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 iron and aggregating α-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 iron by MRI (QSM/R2*) in a more advanced patient population than is being studied in Alterity's randomized Phase 2 trial. Additional information on the open label Phase 2 trial can be found at 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 α-synuclein pathology and preserve nerve cells 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 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 α-synuclein within glia, the support cells of the central nervous system, and neuron loss in multiple brain regions. MSA affects approximately 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'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.

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.