Alterity Therapeutics Announces Expanded ATH434 Phase 2 Clinical Development Program

- Clinical trial to enroll patients with early-stage Multiple Systems Atrophy (MSA) -

- Expanding bioMUSE Natural History Study -

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 19 October 2021: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative conditions, today announced an expansion of the clinical development program for the Company's lead asset, ATH434, in patients with Multiple System Atrophy (MSA), a rare and rapidly progressing Parkinsonian disorder. ATH434 has been shown to reduce abnormal accumulation of α-synuclein by restoring normal iron balance in the brain with the objective of improving motor function in patients with MSA and Parkinson's Disease.

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage MSA. The study will explore the effect of ATH434 treatment on imaging and protein biomarkers such as aggregating α-synuclein and excess iron, which are important contributors to MSA pathology. Several other biomarkers and clinical endpoints will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. Based on consultation with the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and clinical experts in MSA, Alterity has established that patients will receive treatment for 12 months in the Phase 2 study. The longer treatment duration will provide an improved opportunity to detect changes in biomarkers and clinical endpoints to optimize design of a definitive Phase 3 study.

In addition, the Biomarkers of Progression in Multiple Systems Atrophy (bioMUSE) natural history study has reached its original enrollment goal and will be expanded to a total of 20 patients with MSA. The study has proved to be invaluable in generating data to inform and de-risk the Phase 2 trial design, and it will continue to provide longitudinal biomarker and clinical data to characterize disease progression in a patient population that mirrors those to be enrolled in the Phase 2 study.

"With our planned Phase 2 clinical trial and the expansion of bioMUSE, we have created a robust development program to advance ATH434 for the treatment of MSA," said David Stamler, M.D., Chief Executive Officer, Alterity. "By restoring normal iron balance in the brain, ATH434 has the potential to block α-synuclein aggregation, preserve neurons, and treat the underlying pathology of MSA. If successful, this approach to modifying disease progression will have a profound impact on the quality of life for individuals living with MSA, a devastating disease with very few treatment options."

Dr. Stamler, continued, "Importantly, our Phase 2 clinical trial integrates regulatory feedback, expert advice, and critical learnings from bioMUSE to establish an optimal trial design with an

improved overall chance of success. There has been great interest in our program from prospective investigators and we look forward to initiating the trial in the first quarter of calendar year 2022."

The Phase 2, double-blind clinical trial is a three-arm study where early stage MSA patients will be randomized to one of two doses of ATH434 or a placebo, with twice daily dosing. Early-stage patients with a clinical diagnosis of MSA who are ambulatory, have no evidence of severe impairment, and do not have long standing motor symptoms will be enrolled in the study. The trial is expected to enroll 60 early-stage patients in approximately 30 sites in Australia, New Zealand, Europe, and the U.S. As reported last month, the initial results from the Company's bioMUSE natural history study were instrumental in guiding the design of the Phase 2 clinical trial by informing patient selection and confirming that iron content in the brain is a promising biomarker. Based on these data, Alterity believes that treating patients in the early stage of their disease will provide the best chance of improvement from ATH434.

About ATH434

Alterity's lead candidate, ATH434, is the first of a new generation of small molecules 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. In this way, it has excellent potential to treat Parkinson's disease as well as various forms of atypical Parkinsonism such as Multiple System Atrophy (MSA). ATH434 has successfully completed a Phase 1 clinical trial demonstrating the agent is well tolerated, orally bioavailable, and achieved brain levels comparable to efficacious levels in animal models of MSA, with the objective of restoring function in patients with MSA and other Parkinsonian disorders.

ATH434 has been granted Orphan designation for the treatment of MSA by the U.S. FDA and the European Commission.

About bioMUSE

Biomarkers of progression in Multiple Systems Atrophy (bioMUSE) is an ongoing, natural history study that aims to track the progression of patients with MSA, a Parkinsonian disorder without approved therapy. The study is being conducted in collaboration with Vanderbilt University Medical Center in the U.S. under the direction of Daniel Claassen, MD, Associate 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 Phase 2 clinical trial and will be expanded to include a total of 20 patients with MSA. The ongoing study will continue to provide vital information on early stage MSA patients, inform the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy, and deliver clinical data to characterize disease progression in a patient population that mirrors those to be enrolled in the Phase 2 clinical trial.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease characterized by a combination of symptoms that affect both the autonomic nervous system and 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 motor impairment, 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 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]

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 forms of Parkinsonian disorders. Alterity also has a broad drug discovery platform generating patentable chemical 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.

[1]National Institute of Health: Neurological Disorders and Stroke, Multiple Systems Atrophy Fact Sheet

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, uncertainties relating to the impact of the novel coronavirus (COVID-19) pandemic on the company's business, operations and employees, 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.