Alterity Therapeutics Presents Promising Wearable Sensor Data from the bioMUSE Natural History Study at the American Academy of Neurology

- Wearable sensor parameters correlate strongly with clinical scales of motor impairment -

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 26 April 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 that promising wearable sensor data from the *Biomarkers of Progression in Multiple System Atrophy (bioMUSE)* natural history study was presented at the American Academy of Neurology Annual Meeting.

The poster, entitled, *Wearable Sensors for Quantitative Motor Assessments in Multiple System Atrophy*, was presented by Daniel Claassen, MD, Professor of Neurology at Vanderbilt University Medical Center, and Principal Investigator in the bioMUSE study. The analysis was conducted to determine the utility of quantitative wearable sensors in 17 participants with early stage (less than three years of motor symptoms) multiple system atrophy (MSA).

"This analysis from bioMUSE demonstrates that wearable sensors can quantify motor impairment in MSA patients that is not captured by neurological examination," said David Stamler, M.D., Chief Executive Officer, Alterity. "MSA is a devastating condition and use of novel measures to assess disease progression and inform future clinical trials is a win for the entire community. As a result of this natural history study, we have incorporated wearable sensor data into our Phase 2 clinical trial for ATH434 as one of our secondary endpoints to determine the effect of our agent on gait stability. We look forward to additional data from bioMUSE as we strive to better understand the trajectory of MSA and utilize our findings in future clinical trials."

In the study, a strong relationship was evident between sensor parameters and motor assessments. Specifically, sensor parameters correlated strongly with clinical scales of motor impairment and may be useful in assessing disease progression. Importantly, an assessment known as the Timed Up and Go strongly correlated with several gait parameters, including bouts of walking, minutes walking, minutes of standing, and minutes of lying. Because the Timed Up and Go reliably quantifies functional mobility in a clinic setting, the new data suggesting the clinical relevance of these outcomes is important in assessing MSA in the outpatient setting. The results from bioMUSE will inform future trials in MSA as potential outcome measures for disease modifying therapies.

Alterity's medical meeting presentations can be accessed on the Company's website on The Science page.

About bioMUSE

Biomarkers of progression in Multiple System 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 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 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 a randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with early-stage MSA. ATH434 has been granted Orphan designation for the treatment of MSA by the U.S. FDA and the European Commission.

About ATH434 Phase 2 Clinical Trial

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage MSA. The study will evaluate the effect of ATH434 treatment on neuroimaging and protein biomarkers to demonstrate target engagement and clinical endpoints to demonstrate efficacy, in addition to assessments of safety and pharmacokinetics. The selected biomarkers, including brain iron and aggregating α-synuclein, are important contributors to MSA pathology and are therefore appropriate targets to demonstrate drug activity. Wearable sensors will also be employed to evaluate motor activities that are important to patients with MSA. The study is expected to enroll approximately 60 adults to receive one of two dose levels of ATH434 or placebo. Participants will receive treatment for 12 months which will provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive Phase 3 study. Additional information on the Phase 2 trial can be found by ClinicalTrials.gov Identifier: NCT05109091.

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, 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.