Alterity Therapeutics Announces Presentation of Wearable Sensor Data from the bioMUSE Natural History Study at the International Congress of Parkinson's Disease and Movement Disorders

- Wearable sensors strongly correlated with clinical scales on motor impairment -

- bioMUSE Study Validates Use of Wearable Sensors for Alterity's Ongoing Phase 2 Clinical Trial -

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 26 September 2022: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced a poster from the ongoing Biomarkers of Progression in Multiple System Atrophy (bioMUSE) natural history study was presented at the International Congress of Parkinson's Disease and Movement Disorders. The presentation correlates data from wearable sensors with clinical assessments of motor function in individuals with Multiple System Atrophy (MSA).

MSA is a rapidly progressive parkinsonian disorder that results in slowed movements, lack of coordination and difficulty with walking (gait) and balance that predisposes to falls. The poster, entitled *Wearable Sensors for Quantitative Motor Assessments in Multiple System Atrophy*, describes 12 participants from the ongoing bioMUSE study who wore sensors for up to one year to characterize their motor disability in an outpatient setting. In the study, sensor parameters strongly correlated with clinical scales of motor impairment that were largely driven by changes in gait stability. Investigators concluded that step count and walking time are sensitive measures of disease progression in early MSA.

"In this study, we were able to determine that wearable sensors provide a quantitative measurement of MSA progression that is not captured by neurological examination," said Daniel Claassen, MD, Associate Professor of Neurology at Vanderbilt University Medical Center and Principal Investigator in the bioMUSE study. "The level of detail captured by the wearable sensors clearly showed a meaningful slowdown in activity, particularly in patients with rapidly progressive disease. These results provide a tool for physicians to assess the gait and activity levels of their patients, and will inform future trials in MSA as potential outcome measures for disease modifying therapies."

David Stamler, M.D., Chief Executive Officer, Alterity, added, "We are very encouraged by these findings as they validate the use of wearable sensors in our ongoing ATH434 Phase 2 clinical trial in MSA. We are using these sensors in study participants to evaluate motor performance in a real-world setting. Progressive decline in motor function represents an important source of disability in MSA so it is important to have tools to measure it with precision. The data presented demonstrate that we can quantify activity levels of participants to support the outcome of the study."

The poster presentation includes data from n=12 participants who wore a PAMSys device, a validated wearable sensor for continuous monitoring of gait and activity parameters. PAMSys actigraphy sensors were worn continuously for up to 12-months, allowing assessment of gait parameters (step count, bouts of walking, steps per bout, cadence/variability), postures (minutes of sitting, lying, standing, or walking) and postural transitions (sit-to-stand). Clinical assessments were obtained at baseline and months 3, 6, 9 and 12. At each time point, sensor parameters were obtained by averaging data over 14-day periods.

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 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 successfully completed Phase 1 studies demonstrating the agent is well tolerated, orally bioavailable, and achieved brain levels comparable to efficacious levels in animal models of 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 explore the effect of ATH434 treatment on neuroimaging and protein biomarkers, such as excess brain iron and aggregating α-synuclein, which are important contributors to MSA pathology. Clinical endpoints will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. The use of wearable sensors will allow evaluation of motor parameters that are important in patients with MSA. The study is expected to enroll approximately 60 adult patients to receive one of two dose levels of ATH434 or placebo. Patients 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 here: 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 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]National Institute of Health: Neurological Disorders and Stroke, Multiple System Atrophy Fact Sheet

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.