Alterity Therapeutics to Present New Data on ATH434 at the World Orphan Drug Congress USA 2024

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 10 April 2024: 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 new data on ATH434 will be presented at the World Orphan Drug Congress USA 2024 taking place April 23-25, 2024 in Boston, MA.

Title: **Biophysical Characteristics of ATH434, a Unique Iron-Targeting Drug for Treating Friedreich's Ataxia**
Lead Author: Ashley Pall, Department of Pharmaceutical Sciences, Wayne State University

As previously announced, three posters from the Company's development pipeline will also be presented at the American Academy of Neurology (AAN) 2024 Annual Meeting taking place April 13-18, 2024, in Denver, Colorado, USA.

Title: **A Phase 2 Study of ATH434, a Novel Inhibitor of α-Synuclein Aggregation, for the Treatment of Multiple System Atrophy (MSA)**
Lead Author: David Stamler, M.D., Chief Executive Officer of Alterity Therapeutics
Date/Time: Sunday, April 14, from 11:45 a.m. 12:45 p.m. Mountain Time (U.S.)

Title: **Neurofilament Light Chain and Clinical Progression in Early Multiple System Atrophy**
Lead Author: Daniel O. Claassen, M.D., M.S., Professor of Neurology, Vanderbilt University Medical Center
Date/Time: Monday, April 15, from 5:30 p.m. to 6:30 p.m. Mountain Time (U.S.)

Title: **Effects of ATH434, a Clinical-phase Small Molecule with Moderate Affinity for Iron, in a Parkinson's Disease Model in Macaques**
Lead Author: Margaret Bradbury, Vice President, Research and Nonclinical Development, Alterity Therapeutics
Date/Time: Tuesday, April 16, from 11:45 a.m. to 12:45 p.m. Mountain Time (U.S.)

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

About ATH434-201 Phase 2 Clinical Trial

The ATH434-201 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. Selected biomarkers, such as brain iron and aggregating α-synuclein, are important contributors to MSA pathology and are therefore appropriate targets to demonstrate drug activity. Wearable sensors have also been employed to evaluate motor activities that are important to patients with MSA. The study enrolled 77 adults who were randomly assigned 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 bioMUSE

Biomarkers of progression in Multiple System Atrophy (bioMUSE) is a natural history study that aims to track the progression of individuals 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, M.D., M.S., 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 randomized ATH434-201 Phase 2 clinical trial and enrolled approximately 20 individuals with clinically probable or clinically established MSA. BioMUSE continues to provide vital information on early stage MSA patients, informs the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy, and delivers clinical data to characterize disease progression in a patient population that mirrors those currently enrolling 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 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 Parkinson's Disease

Parkinson's disease (PD) is the second most common neurodegenerative disorder and causes unintended or uncontrollable movements of the body along with neuropsychiatric and other nonmotor features. The precise cause of PD is unknown, but some cases are hereditary while others are thought to occur from a combination of genetics and environmental factors that trigger the disease. In PD, brain cells become damaged or die in the substantia nigra, the part of the brain that produces dopamine--a chemical needed to produce smooth, purposeful movement. The cardinal symptoms of PD are tremors, rigidity, slowing of movements, and later in disease, impaired balance. Other symptoms may include difficulty swallowing, chewing, or speaking; emotional changes; urinary problems or constipation; dementia or other cognitive problems; fatigue; and problems sleeping.[3] Nearly one million people in the U.S. and more than 10 million people worldwide are living with PD. Approximately 60,000 Americans are diagnosed with PD each year.[4]

[1]Beauchamp et al, "ATH434 Rescues Pre-motor Hyposmia in a Mouse Model of Parkinsonism, *Neurotherapeutics*, DOI:10.1007/s13311-022-01300-0
[3]National Institute of Health: Neurological Disorders and Stroke, Parkinson's Disease Information Page; [4]Parkinson's Foundation

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 and is currently being evaluated in two Phase 2 clinical trials in Multiple System Atrophy. Alterity also 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 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.