



## **Alterity Therapeutics Presents New Data on Multiple System Atrophy, a Rare Parkinsonian Disorder**

- Presentations Convey Novel Approach for Improving Diagnostic Accuracy and Tracking Disease Severity in MSA -

- Data Presented at the International Congress of Parkinson's Disease and Movement Disorders -

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 31 August 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 presentations from its bioMUSE natural history study of Multiple System Atrophy (MSA) were delivered at the International Congress of Parkinson's Disease and Movement Disorders (MDS) taking place August 27 - 31, 2023 in Copenhagen, Denmark.

The posters presented from Alterity's bioMUSE study address the need for incorporating biomarkers as a critical component for diagnosis of MSA. The diagnosis of early MSA can be challenging as individuals often present similarly to Parkinson's disease (PD). In contrast to PD, MSA is rapidly progressive and, therefore, it is vital to accurately diagnose patients enrolling in clinical trials.

“The approach of using a diverse set of biomarkers to augment clinical criteria for MSA will greatly improve the diagnosis of this devastating disease,” said David Stamler, M.D., Chief Executive Officer of Alterity. “Based on our collaboration with the clinical and neuroimaging experts from Vanderbilt, we are in a unique position to implement this strategy in our ATH434-201 Phase 2 clinical trial. Our unique protocol design is helping ensure we are enrolling the right patient population thus giving ATH434 the best chance at success.”

Daniel O. Claassen, M.D., M.S., Professor of Neurology, Vanderbilt University Medical Center, added, “As with any disease, accurate diagnosis is critical to provide the best treatment options for patients, and because MSA is a rare, rapidly progressing disease, timing is of the essence. Diagnosis of early-stage MSA is vital for maximizing neuronal preservation with disease modifying therapies, and thus identifying biomarkers for early pathology is critical. Our findings presented this week support the use of specialized MRI techniques and fluid biomarkers to improve the specificity of MSA diagnosis as well as assess clinical measures of disease severity and treatment response in MSA.”

Two poster presentations were given at the MDS Congress.

The poster entitled, “A multimodal approach for diagnosis of early Multiple System Atrophy” was presented by Dr. Claassen. The analysis describes three clinically probable MSA patients with divergent MRI and fluid biomarker data, supporting the use of biomarkers to improve diagnostic

accuracy in early MSA. The presented cases demonstrate that no single biomarker can be relied upon to aid in the diagnosis of early MSA. In addition, divergent clinical and biomarker findings in this case series suggests a multimodal clinical-biomarker approach is required for accurate diagnosis of clinically probable or early MSA. These examples support application of clinical and quantitative biomarkers in clinical trials evaluating disease-modifying treatments for early MSA.

The poster entitled, “Preliminary evidence for evolution of myoinositol and N-acetylaspartate as biomarkers of disease severity in early-stage Multiple System Atrophy” was presented by Paula Trujillo Diaz, PhD, Research Assistant Professor, Department of Neurology, Vanderbilt University Medical Center. The study assessed 13 early-stage MSA patients (motor symptoms  $\leq$  3 yrs) with diagnosis based on clinical parameters, fluid biomarkers, and quantitative MRI for iron deposition. The investigators then applied a non-invasive MRI technique known as magnetic resonance spectroscopy (MRS) that allows metabolite quantification in the brain, including myoinositol (ml; a marker of gliosis) and N-acetylaspartate (NAA; a marker of neuronal integrity). The results suggest that an increase in ml/water and decrease in NAA/water decrease over one-year in patients with MSA is consistent with MSA pathology. The findings suggest that metabolite concentration by MRS may be useful biomarkers for assessing clinical measures of disease severity and treatment response In MSA.

The poster presentations can be accessed on the Published Scientific Research section of the Alteryx website [here](#).

### **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 Alteryx’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  $\alpha$ -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.<sup>1</sup>

<sup>1</sup>[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 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](http://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.*