



## **Alterity Announces Presentation of Biomarker Data at the International Parkinson and Movement Disorder Society Congress 2021**

### ***Study Results Successfully Inform the Design of ATH434 Phase 2 Clinical Trial***

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 20th September 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 that data was presented from the Company’s Biomarkers of progression in Multiple System Atrophy (bioMUSE) study at the International Parkinson and Movement Disorder Society Virtual Congress 2021 being held September 17-22, 2021.

BioMUSE is a natural history study that is tracking disease progression in individuals with early Multiple System Atrophy (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.

The poster, entitled, “*Non-invasive imaging markers of iron accumulation in Multiple System Atrophy*”(Abstract:563; Category: Parkinsonism, Atypical - MSA), describes the use of advanced MRI methods to quantify iron accumulation in early MSA patients. The advanced methods employed in the study, referred to as quantitative susceptibility mapping (QSM), demonstrated pathological iron accumulation in multiple areas of the brain in patients with early MSA. The study investigators concluded that QSM may improve patient selection in clinical trials of disease modifying therapy and has potential to serve as a biomarker for assessing treatment induced changes.

“The initial data from bioMUSE have been vital in advancing our Phase 2 trial with ATH434,” said David Stamler, M.D., Chief Executive Officer, Alterity. “The study has accomplished what we had hoped: It has informed patient selection in Phase 2 and it has confirmed that iron content in the brain is a promising biomarker in our target population. By employing QSM in both ways, we can de-risk the Phase 2 study and improve our overall chance of success.”

Dr. Claassen, added, “Iron accumulation is central in MSA pathogenesis due to its ability to promote  $\alpha$ -synuclein aggregation and oxidative stress, and our analysis revealed higher iron concentrations in MSA patients compared to patients with Parkinson’s disease. Importantly, we also found that increased iron in the brain is a determinate for severity of disease in MSA. The data presented also confirms our belief that early diagnosis of MSA is vital for maximizing preservation of brain neurons with disease modifying therapies.”

The objective of the study is to define the localization and extent of iron accumulation in patients with early multiple system atrophy (MSA). The study enrolled patients with MSA (n=9), Parkinson’s Disease (n=17) and healthy controls (n=18). All MSA patients had evidence of parkinsonism, autonomic dysfunction, pyramidal findings and/or ataxic findings on exam. All Parkinson’s Disease participants met UK Brain health criteria for diagnosis and were of similar age to the MSA and healthy control cohorts.

The bioMUSE study will continue to enroll and follow patients for 12 months and is expected to continue to provide a rich source of information regarding the Phase 2 study expected to commence later this year.

The poster presentation is available on the Alterity website [here](#).

### **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 will provide vital information on early stage MSA patients to optimize the design of Alterity's Phase 2 clinical trial in MSA. The study will also inform the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy.

### **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 to reduce abnormal accumulation of  $\alpha$ -synuclein in animal models of disease 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 been granted Orphan designation for the treatment of MSA by the US FDA and the European Commission.

### **About Multiple System Atrophy**

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease with no approved therapy. It is rapidly progressive and causes profound disability. MSA is a Parkinsonian disorder characterized by motor impairment typical of Parkinson's disease; autonomic instability that affects involuntary functions such as blood pressure maintenance and bladder control; and impaired balance and/or coordination that predisposes to falls. MSA affects approximately 15,000 patients in the U.S. A pathological hallmark of MSA is the accumulation of  $\alpha$ -synuclein within oligodendroglia cells (glial cytoplasmic inclusions) and neuron loss in multiple brain regions.

### **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](http://www.alteritytherapeutics.com).

## Authorisation & Additional information

This announcement was authorized by David Stamler, CEO of Alterity Therapeutics Limited.

### Contact: Investor Relations

Australia

Rebecca Wilson

E: WE-AUAlterity@we-worldwide.com

Tp: +61 417 382 391

US

Remy Bernarda

remy.bernarda@iradvisory.com

Tp: +1 (415) 203-6386

### 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.*