

# Alterity Therapeutics Announces Presentation of ATH434 at the American Autonomic Society Virtual Meeting 2021

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 9 November 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 a poster presentation and accompanying video were delivered at the American Autonomic Society 32<sup>nd</sup> Annual Internation Symposium on the Autonomic Nervous System.

The poster, entitled, Cardiovascular safety and pharmacokinetics of ATH434, a novel small molecule inhibitor of  $\alpha$ -synuclein aggregation, in adults and older adults, described results from the Company's Phase 1 clinical trial conducted in healthy volunteers. In the Phase 1 trial, ATH434 was well tolerated in adult and  $\geq$  65 year-old volunteers and demonstrated no cardiac adverse event signal and no clinically significant changes in blood pressure or heart rate at any dose. ATH434 also demonstrated dose dependent pharmacokinetics (PK) after single and multiple oral doses and a half-life that supports twice-daily dosing.

"The promising safety profile and oral bioavailability of ATH434 supports our Phase 2 clinical trial design in patients with multiple system atrophy (MSA)," said David Stamler, M.D., Chief Executive Officer, Alterity. "We believe that the option for administration in pill form may provide a convenient treatment option for individuals with MSA. We look forward to initiating our Phase 2 clinical trial in MSA in the first quarter of next year."

In addition, Daniel Claassen, MD, gave a plenary lecture on the imaging methods for MSA which included findings from Alterity's Biomarkers of progression in Multiple System Atrophy (bioMUSE) natural history study, available <a href="here">here</a>. Dr. Claasen is Associate Professor of Neurology, Vanderbilt University Medical Center and Principal Investigator of bioMUSE.

Alterity's poster presentation and accompanying video will be available on the Company's website.

## **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  $\alpha$ -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 has successfully completed a Phase 1 clinical trial demonstrating the agent is well tolerated, orally bioavailable, and achieved brain levels comparable to efficacious levels in animal models of MSA, with the objective of restoring function in patients with MSA and other Parkinsonian disorders.

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

### 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 a combination of symptoms that affect both the autonomic nervous system and 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 motor impairment, 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 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.  $^1$ 

<sup>1</sup>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 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 <a href="https://www.alteritytherapeutics.com">www.alteritytherapeutics.com</a>.

## **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.