

# Alterity Therapeutics Issues Shareholder Letter Highlighting Pipeline Advances and Key Upcoming Milestones

Preliminary Data from ATH434-202 Study Expected in 1H 2024 –
ATH434-201 Study to Complete in November 2024 –

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 22 January 2024:** Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today issued a letter to shareholders.

Dear Shareholders:

As we begin a new year, I wanted to take a moment to thank you for your support of Alterity, reflect on our accomplishments in 2023, and layout our key milestones for 2024. We remain steadfastly committed to developing new treatments for individuals living with neurodegenerative diseases.

# 2023 was a critical year for us and I am pleased to report that we hit all of our intended milestones.

We have an extremely robust program evaluating neurodegenerative diseases with a current focus on Multiple System Atrophy, or MSA, a disease related to Parkinson's. As a reminder, MSA is a rare and aggressive Parkinsonian disorder that rapidly progresses and causes profound disability. Although similar to Parkinson's disease, affected individuals cannot adequately maintain their blood pressure or control bowel and bladder function – areas that drastically impair quality of life. The pathological hallmark of MSA is accumulation of the protein alphasynuclein and neuron loss in multiple brain regions within the central nervous system. While some of the symptoms of MSA can be treated with available medications, currently there are no drugs that can slow disease progression and there is no cure.

We are looking to change the paradigm of treating MSA with our lead clinical development candidate ATH434, an orally administered agent discovered in house to target neurodegeneration. ATH434 acts by *redistributing* excess iron in the brain, *reducing* the protein  $\alpha$ -synuclein, and *rescuing* neuronal function. Based on accumulated pre-clinical data and an understanding of how MSA develops and progresses, we believe ATH434 has excellent potential

to treat MSA as well as Parkinson's disease. Importantly, ATH434 has been granted Orphan Drug Designation (ODD) for the treatment of MSA by the U.S. FDA and the European Commission. ODD comes with many benefits including 7-10 years of market exclusivity, tax credits and fee reductions, as well as protocol assistance from each agency.

Our primary Phase 2 clinical trial is a randomized, double-blind placebo-controlled study (ATH434-201) evaluating ATH434 in individuals with *early-stage* MSA. I am very proud of our 201 study team for fulfilling our goals in 2023 by opening numerous clinical trial sites around the world and completing enrollment of all study participants in November 2023. **The ATH434-201** study is treating these participants for 12 months and, therefore, the study will complete in November 2024. Once this portion of the trial is completed, we will then analyze the data and report topline results in January 2025.

In addition, during 2023 we also initiated a second, Phase 2 clinical trial (ATH434-202) in individuals with *more advanced* MSA than in the 201 trial. A key aim of the 202 study is to assess the efficacy of ATH434 on objective biomarkers that measure target engagement and are relevant to the underlying pathology of MSA. While the 202 trial is also treating participants for 12-months, it has an open label design that will allow us to perform interim analyses of biomarker data while the study is ongoing, giving us a potential early indication of efficacy. **We expect to report preliminary six-month data from the initial patients enrolled in the ATH434-202 trial in the first half of this year.** 

Our bioMUSE Natural History study also continues to generate invaluable data related to the understanding of MSA and its early presentation. The insights gained from this study enabled us to refine the design of our ongoing Phase 2 studies, optimizing patient selection and analysis of key endpoints. Along with our academic partners at Vanderbilt University Medical Center in the U.S., we have delivered several data presentations at important neurology conferences during 2023. Important elements of the data included an enhanced understanding of MSA, new methods to diagnose and potentially treat the disease, and potential novel biomarkers for evaluating disease modifying treatments such as ATH434. We expect to report additional data from bioMUSE this year as well.

In December 2023, we presented promising new data on the effect of ATH434 in a Parkinson's disease primate model. Personally, I am very excited about these findings because we have shown for the first time that ATH434 can reduce Parkinson's symptoms in a higher order animal – the monkey. Importantly, the improvements in motor skills and general functioning that parallel human parkinsonism were associated with reductions in iron in affected brain regions, validating the approach we are using in our ongoing clinical trials.

As I have laid out above, **2024 will be a pivotal year for us.** The primate data in Parkinson's disease has improved our ability to predict clinical outcomes and increases our overall confidence

level in our ongoing Phase 2 clinical trials in MSA. We are currently running two trials allowing us to study MSA populations of differing severity. Our ATH434-201 clinical trial will complete in November with topline data reported shortly thereafter. We will also be able to report preliminary data from our ATH434-202 trial in the first half of this year. And, we expect to make additional progress with bioMUSE and the advancement of ATH434 in Parkinson's disease.

Thank you for your continued interest and support and we look forward to keeping you updated on our progress.

David Stamler, M.D., Chief Executive Officer of Alterity

## **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 <u>www.alteritytherapeutics.com</u>.

#### **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.