



Alterity commences enrolling Multiple System Atrophy patients in bioMUSE Study

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 27th October 2020: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) (“Alterity” or “the Company”) today announced it has commenced enrolling patients with Multiple System Atrophy (MSA) in its bioMUSE Study in the United States.

BioMUSE is a 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 US 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 study in MSA. The study will also inform the selection of biomarkers suitable to evaluate target engagement and preliminary efficacy.

Alterity’s lead compound ATH434 has already successfully completed Phase 1 clinical trial and is advancing toward a Phase 2 clinical trial.

Dr. Claassen said: “This is an important study to expand our understanding of MSA. We are enrolling early stage patients who stand to gain the most from disease modifying treatments. I look forward to working with Alterity on this project and I hope it can provide the foundation for advancing treatments such as ATH434 into the clinic.”

MSA is a neurodegenerative disease with major sources of disability resulting from motor symptoms characteristic of Parkinson’s disease and impaired ability to maintain normal blood pressure, bowel function and bladder control. Current treatment includes medications and lifestyle changes to help manage symptoms, but there is no treatment of the underlying cause and no cure.

The study is enrolling early stage MSA patients and will track changes in clinical measures and biomarkers for up to one year. Over the course of the study, patients will undergo comprehensive evaluation with detailed neurological examination and clinical rating scales of motor, autonomic and activities-of-daily-living symptoms along with specialized neuroimaging and assessment of protein biomarkers in diverse biological specimens.

Data from bioMUSE will also be used to inform patient selection in Alterity’s upcoming Phase 2 clinical trial of ATH434, its lead clinical candidate for the treatment of MSA. The US FDA has encouraged Alterity to utilize data from the bioMUSE study to aid in the development of efficacy endpoints for the Phase 2 study.

Vanderbilt University Medical Centre is one of the largest academic medical centres in the southeast US managing more than 2 million patients each year. The School of Medicine’s biomedical research program is among the nation’s top 10 in terms of National Institutes of Health peer review funding.

Dr David Stamler, Chief Medical Officer, added: “As we prepare for our Phase 2 study, the data from bioMUSE will provide key information to help us optimize the study design. Starting this study brings us one step closer to finding novel treatments for this devastating condition.”

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Authorization & Additional information

This announcement was authorized by Geoffrey Kempler, Chairman and CEO of Alterity Therapeutics Limited.

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About Alterity Therapeutics Limited and ATH434

Alterity's lead candidate, ATH434 (formerly PBT434), 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 α -synuclein and tau proteins in animal models of disease by redistributing labile iron in the brain. In this way, it has potential to treat Parkinson's disease and atypical forms of Parkinsonism such as Multiple System Atrophy (MSA) and Progressive Supranuclear Palsy (PSP).

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

For further information please visit the Company's web site at www.alteritytherapeutics.com.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare and rapidly progressive neurological disorder affecting adults. It has no known cause. In addition to presenting with motor symptoms like those in Parkinson's disease, individuals with MSA may also experience loss of ability to coordinate voluntary movements and impaired regulation of involuntary body functions such as blood pressure, bowel and bladder control. Most of these symptoms are not addressed by available drugs for patients with Parkinson's disease. As the condition progresses, daily activities become increasingly difficult and complications such as increased difficulty swallowing, vocal cord paralysis, progressive immobility, and poor balance become more prominent. Symptoms tend to appear after age 50 and rapidly advance, leading to profound disability and death.

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 (formerly PBT434), 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 patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to ATH434.

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 updated 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.