Alterity Therapeutics announces funding from Michael J. Fox Foundation for ATH434 dose optimization for Parkinson's disease clinical trials

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 9th February 2021: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company") has today announced the award of a grant from The Michael J. Fox Foundation for Parkinson's Research to determine optimal dosing of its lead drug candidate ATH434 for Parkinson's disease (PD) based on imaging of brain iron.

The funding for US$495,000 will be used to evaluate the pharmacologic profile of ATH434 in a primate model to determine the optimal dose of ATH434 in future Parkinson's disease clinical trials. This is the second grant that Alterity has received from The Michael J. Fox Foundation to support the development of ATH434 in PD.

Alterity Chief Executive Officer Dr David Stamler said, "The Michael J. Fox Foundation is an incredible organisation at the frontier of research and treatment innovation for Parkinson's disease, which remains incurable and affects an estimated 7-10 million people worldwide[i]."

"ATH434 targets alpha-synuclein misfolding and aggregation through the redistribution of excess labile iron, and our first indication Multiple System Atrophy (MSA) is on track to start its phase 2 clinical trial later this year. The potential to expand into other Parkinsonian disorders that implicate alpha-synuclein has always been part of our strategy and this funding allows us to take another step towards realizing a program in Parkinson's disease."

Parkinson's disease (PD) is the second most common age-related neurodegenerative disorder after Alzheimer's disease and occurs when brain cells that make dopamine, a chemical that underlies control of movement, degenerate and ultimately die. Because Parkinson's disease can cause tremor, slowness, stiffness, and problems with balance and walking, it is called a "movement disorder." But non-motor symptoms such as constipation, depression, and impaired memory can also be part of PD. It is a lifelong and progressive disease, which means that symptoms slowly worsen over time.[ii]

While available therapies can treat some symptoms, people with Parkinson's urgently need new treatments to slow or stop disease progression and improve quality of life.

Dr Werner Poewe, Professor of Neurology at the Medical University Innsbruck, Austria, said, "By targeting alpha-synuclein, ATH434 has potential to modify the course of synucleinopathies such as Parkinson's disease and MSA.

"Aggregates of misfolded alpha-synuclein protein are widely distributed in the brains of individuals affected by these disorders, and by reducing their build-up ATH434 has potential to improve the motor and non-motor symptoms of these devastating conditions. I look forward to seeing the results from the dose optimization studies for PD clinical trials and future development in this indication."

The project will be led by Margaret Bradbury, PhD, Vice President, Nonclinical Development, in collaboration with Daniel Claassen, MD, Associate Professor of Neurology at Vanderbilt University Medical Center and David Finkelstein, PhD, who heads the PD Research Laboratory at the Florey Institute of Neuroscience and Mental Health.

The Michael J. Fox Foundation is dedicated to finding a cure for Parkinson's disease through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson's today.

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Authorization & Additional information
This announcement was authorized by David Stamler, 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 website 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.

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 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.

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[i] Ref: Parkinson's Disease Statistics - Parkinson's News Today

[ii] Ref: Parkinson's 101 | Parkinson's Disease (michaeljfox.org)