Alterity Therapeutics Launches ATH434 Phase 2 Clinical Trial for the Treatment of Patients with Multiple System Atrophy

Multiple System Atrophy is a rare, rapidly progressive, neurodegenerative disease that causes profound disability

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 2 June 2022: Alterity Therapeutics (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company"), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced the Company's Phase 2 clinical trial of ATH434 for the treatment of patients with Multiple System Atrophy (MSA) is now open for enrolment in New Zealand.

MSA is a rare neurodegenerative disease. While it is similar to Parkinson's disease, MSA progresses more rapidly and causes profound disability. In addition to the motor symptoms characteristic of Parkinson's disease, MSA manifests with more severe autonomic nervous system impairment resulting in bladder dysfunction and the inability to maintain normal blood pressure, as well as uncoordinated or clumsy movements that contribute to falling. Currently available treatments only address certain symptoms of MSA. There are no therapies that slow disease progression and there is no cure.

ATH434 is designed to reduce the toxic accumulation of α-synuclein, a pathological hallmark of MSA, and preserve nerve cells by restoring normal iron balance in the brain. Therefore, ATH434 has the potential to address the underlying pathology of the disease and preserve function in individuals with MSA.

"The advancement of our ATH434 program underscores our commitment to bring a much needed treatment to individuals with MSA," said David Stamler, M.D., Chief Executive Officer, Alterity. "The opening of enrolment for our Phase 2 in New Zealand is an important first step for this clinical program, and I am grateful to our team and our investigators who supported the launch of the trial. Over the course of this year, we will expand the trial into other regions globally."

About ATH434 Phase 2 Clinical Trial

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled investigation of ATH434 in patients with early-stage MSA. The study will explore the effect of ATH434 treatment on imaging and protein biomarkers, such as aggregating α-synuclein and excess iron, which are important contributors to MSA pathology. Clinical and biomarker endpoints, including use of wearable sensors, will permit comprehensive assessment of ATH434 efficacy along with characterization of safety and pharmacokinetics. The use of wearable sensors will allow evaluation of motor parameters that are important in patients with MSA. The study is expected to enroll approximately 60 adult patients to receive one of two doses of ATH434 or placebo.

Patients will receive treatment for 12 months which will provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive Phase 3 study. Additional information on the Phase 2 trial can be found by ClinicalTrials.gov Identifier: NCT05109091.

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 α-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 Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease characterized by failure of the autonomic nervous system and impaired 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 a variable combination of slowed movement and/or rigidity, 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 α-synuclein within glia, 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]

[1]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 Parkinsonian disorders. Alterity also has a broad drug discovery platform generating patentable chemical compounds 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.

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.