



Alterity Therapeutics Receives FDA End-of-Phase 2 Meeting Minutes Confirming Registrational Pathway for ATH434 in Multiple System Atrophy

- Official FDA minutes confirm the previously announced End-of-Phase 2 meeting outcomes and provide additional detail on the planned Phase 3 protocol –*
- FDA agreed that a single pivotal Phase 3 trial plus confirmatory evidence could support an approval of ATH434 for the treatment of MSA –*
- Pivotal Phase 3 trial activities on track to initiate by year-end 2026 –*

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 7 July 2026: [Alterity Therapeutics](#) (ASX: ATH, NASDAQ: ATHE) (“Alterity” or “the Company”), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced that it has received the official meeting minutes from its End-of Phase-2 (EOP2) meeting for ATH434 in Multiple System Atrophy (MSA) from the U.S. Food and Drug Administration (FDA). The minutes confirm the key elements of the registrational Phase 3 program previously announced on 9 June 2026 and the path toward a potential New Drug Application (NDA) filing.

“The official meeting minutes confirm the alignment we reached with the FDA and provide a well-defined clinical development strategy for registration,” said David Stamler, M.D., Chief Executive Officer. “The FDA’s willingness to accept a single pivotal trial supported by confirmatory evidence reflects a clear pathway for ATH434 in MSA. With the Phase 3 design elements confirmed, we are finalizing the protocol and remain on track to initiate Phase 3 trial activities by year-end 2026.”

Dr. Daniel Claassen, MD, Chief Medical Advisor, commented: “The Phase 2 results for ATH434 were among the most encouraging I have seen in the field, and the alignment reached with the FDA on the Phase 3 trial design is an important next step in bringing a meaningful new treatment option to people living with this devastating disease.”

The EOP2 minutes confirmed that the FDA agreed with the proposed Phase 3 trial design, including the study population, treatment regimen, and efficacy endpoints. Alignment was reached on the selection and analysis of the primary endpoint – the 11-item UMSARS Part I¹ rating scale, a functional measure of activities of daily living affected in MSA. Agreement was also reached on selection of key secondary endpoints, including the Swallowing Disturbance Questionnaire (SDQ), the Orthostatic Hypotension Symptom Assessment (OHSA), and the Clinical Global Impression of Severity (CGI-S). The Phase 3 study is expected to enroll approximately 200

patients who will be randomized in a 1:1 ratio and treated with ATH434 50 mg or matching placebo twice daily for 12 months.

The FDA further indicated that a single pivotal trial plus confirmatory evidence could provide the necessary data to support an approval of ATH434 for the treatment of MSA. Alterity expects that the data from its ATH434-201 Phase 2 clinical trial will provide the required confirmatory evidence. The FDA also indicated that the anticipated size of Alterity's safety database at the conclusion for the Phase 3 was reasonable. A single pivotal trial provides an efficient route to completion of the clinical development program and potential filing of an NDA, both in time and resources required. The Company also plans to offer an open label extension to participants who complete the Phase 3 trial to continue their treatment and enhance the safety database for ATH434.

About ATH434

Alterity's lead candidate, ATH434, is an oral agent designed to reduce iron accumulation and inhibit abnormal protein aggregation associated with neurodegeneration. ATH434 has been shown to reduce α -synuclein pathology and preserve neuronal function by restoring normal iron balance in the brain in preclinical models. As an iron chaperone, it has excellent potential to treat Parkinson's disease as well as various Parkinsonian disorders such as Multiple System Atrophy (MSA). Positive results from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with MSA demonstrated robust clinical efficacy, target engagement as indicated by key biomarkers, and a favorable safety profile. Positive data from a second Phase 2 open-label biomarker trial in patients with more advanced MSA reinforced these results. ATH434 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), and Orphan Drug Designation by the FDA and the European Commission for the treatment of MSA.

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 that causes profound disability. MSA is a Parkinsonian disorder characterized by a variable combination of slowed movement and/or rigidity, autonomic dysfunction affecting involuntary functions such as blood pressure maintenance and bladder control, and impaired balance and/or coordination that predispose patients to falls. A pathological hallmark of MSA is the accumulation of abnormal clumping of the protein α -synuclein within oligodendrocytes, the myelin-producing support cells of the central nervous system, along with progressive neuronal loss in multiple brain regions. MSA affects up to 50,000 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.²

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 is focused on developing disease modifying therapies in Multiple System Atrophy (MSA) and related Parkinsonian disorders. Alterity is preparing to initiate a Phase 3 pivotal trial in MSA, a rare and rapidly progressive disease. ATH434, the Company's lead asset, has demonstrated clinically meaningful efficacy in a randomized, double-blind, placebo-controlled Phase 2 clinical trial in participants with MSA. Alterity has further reported positive data in its open label Phase 2 clinical trial in participants with advanced MSA. In addition, Alterity 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 website at <https://alteritytx.com>.

References

¹ 11-item UMSARS Part I (previously described as modified UMSARS I): Unified Multiple System Atrophy Rating Scale, 11-Items include: Orthostatic symptoms, Swallowing, Speech, Handwriting, Cutting food, Dressing, Hygiene, Walking, Falling, Urinary and Bowel function.

² [Multiple System Atrophy | National Institute of Neurological Disorders and Stroke \(nih.gov\)](#)

Authorization & Additional information

This announcement was authorized by the Board of Directors 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.