



## **Alterity Therapeutics Receives Positive FDA Feedback Following Second Type C Meeting on ATH434 Phase 3 Program in Multiple System Atrophy**

*– Alignment reached on chemistry, manufacturing, and control (CMC) elements of ATH434 Phase 3 development program –*

*– Positive feedback supports readiness for Phase 3 initiation with manufacturing scale-up progressing in parallel –*

*– End-of-Phase 2 meeting with FDA remains on track for mid-2026 –*

**MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 27 April 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 it has received positive regulatory feedback following a Type C Meeting with the U.S. Food and Drug Administration (FDA) regarding its planned Phase 3 development program for ATH434 in Multiple System Atrophy (MSA). MSA is a rare, rapidly progressive neurodegenerative disease with no approved disease-modifying treatments.

This second Type C Meeting builds on Alterity’s recent regulatory interactions with the FDA and represents a further step towards readiness for the planned Phase 3 pivotal trial in MSA. Alterity received written feedback supporting its plans related to the chemistry, manufacturing, and control (CMC) elements of the program. The first Type C Meeting, which was announced in March, related to clinical pharmacology and non-clinical development aspects of the program.

“Confirming alignment with the FDA on the chemistry and manufacturing of ATH434 represents another critical step toward initiation of our Phase 3 program,” said David Stamler, M.D., Chief Executive Officer of Alterity. “The FDA endorsed our plans related to the manufacture and testing of ATH434 for use in our Phase 3 trial and ultimately for commercialization, if approved. We continue to advance ATH434 through the necessary steps to initiate our pivotal development program, and we look forward to finalizing our plans with the FDA at an End-of-Phase 2 meeting that remains on track for mid-year 2026.”

### **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>.

### **Authorisation & 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.*