Alterity Therapeutics Announces Successful Completion of Phase 1 Clinical Trial

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – Monday 29 July 2019. Alterity Therapeutics Limited (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company") today announced that it has successfully completed its Phase 1 study of PBT434, a novel, orally bioavailable small molecule inhibitor of alpha-synuclein aggregation.

Alpha-synuclein, when aggregated in the brain, is a pathological hallmark of Parkinsonian conditions and is considered an important biologic target for treating these neurodegenerative diseases.

The completed trial, which now includes data from elderly volunteers receiving repeated doses, continues to demonstrate that the drug was safe and well-tolerated, with adverse event rates comparable to placebo. It builds on the data from healthy volunteers announced in May 2019 at the American Academy of Neurology Annual Meeting.

Systemic exposure to the drug was comparable between elderly and healthy volunteers. This information, along with previous results in the Phase 1 study, indicate that clinically tested doses achieve concentrations in the brain that are comparable with those associated with efficacy in animal models of disease.

As was observed in healthy adult volunteers, no elderly subject experienced a serious adverse event or an adverse event that led to discontinuation of the study drug.

Dr David Stamler, Chief Medical Officer and Senior VP Clinical Development, said: "We are very pleased that the excellent safety and tolerability profile in the adult population has now been extended to elderly volunteers. These data will provide the foundation for our interactions with regulatory authorities later this year as we advance the program toward a Phase 2 clinical trial."

PBT434 is an oral small molecule drug candidate with potential for treating synucleinopathies such as Parkinson disease and Multiple system atrophy, a form of atypical Parkinsonism. Multiple system atrophy is a rare and rapidly progressive neurological disorder affecting adults. PBT434 was granted Orphan designation by the U.S. FDA earlier this year for the treatment of Multiple system atrophy.

The Phase 1 Clinical Trial for PBT434 recruited healthy adult and elderly (≥ 65) volunteers with the primary goals of assessing the safety and tolerability of PBT434 after single and multiple oral dose administration. Secondary goals included evaluating pharmacokinetics in plasma and cerebrospinal fluid that enabled determination of how PBT434 is absorbed and metabolized by the body.

PBT434 is the first of a new generation of small molecules designed to block the accumulation and aggregation of α-synuclein. Alterity is already in the preparatory phase of planning for Phase 2 clinical trial and will provide further updates to the market in the coming months.

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About Alterity Therapeutics Limited

Alterity's lead candidate, PBT434, is the first of a new generation of small molecules designed to inhibit the aggregation of pathological proteins implicated in neurodegeneration. PBT434 has been shown to reduce abnormal accumulation of α-synuclein and tau proteins in animal models of disease by restoring normal iron balance in the brain. In this way, it has excellent potential to treat various forms of atypical Parkinsonism such as Multiple System Atrophy (MSA) and Progressive Supranuclear Palsy (PSP).

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

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, 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, PBT434, 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, PBT434, 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 PBT434.

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.