Alterity's lead drug candidate receives positive opinion from European medical agency

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – Monday 18 November 2019. Alterity Therapeutics Limited (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company") has received a positive opinion from the European Medicines Agency's Committee for Orphan Medicinal Products (COMP) on recommending the designation of its lead molecule PBT434 for the treatment of Multiple System Atrophy (MSA) as an orphan medicinal product to the European Commission (EC).

Following the finalisation of relevant documents, COMP has forwarded the opinion to the EC for its decision on the recommendation.

"We are pleased to receive the positive opinion from COMP for PBT434 as a potential treatment for MSA in Europe," said Geoffrey Kempler, CEO of Alterity. "Europe is a key market for Alterity, and it will lay the foundation for the Company to expand the use of PBT434 into other markets. We look forward to hearing more from the EC on their decision and will keep our stakeholders updated on progress."

In January this year, the US Food and Drug Administration (FDA) granted PBT434 orphan drug status for the treatment of MSA.

Phase 1 clinical trial results for PBT434 were announced in July. PBT434 was found to be safe and well-tolerated in adult and older adult (≥ 65 years) subjects with an adverse event profile comparable to placebo. The clinically tested doses achieved concentrations in brain that are potentially clinically relevant.

PBT434 looks to treat Parkinsonian disorders such as Parkinson's disease (PD) and MSA. These neurogenerative diseases result from accumulation of aggregated alpha-synuclein protein. PBT434 was found to inhibit the alpha-synuclein aggregation, preserve neurons and improve motor function in pre-clinical models of PD and MSA.

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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.