European Commission approves Orphan Designation for Alterity's lead drug candidate

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 14 January 2020. Alterity Therapeutics Limited (ASX: ATH, NASDAQ: ATHE) ("Alterity" or "the Company") announces that the European Commission (EC) has granted Orphan Drug designation for its lead molecule, PBT434, for the treatment of Multiple System Atrophy (MSA).

Orphan Drug designation by the EC entitles Alterity to ten years of market exclusivity in the European Union for the use of PBT434 in the treatment of MSA and other benefits including assistance in developing clinical protocols, reduced fees and access to EU-funded research grants.

The approval was based on the recommendation of a positive opinion from the European Medicines Agency's Committee for Orphan Medicinal Products, which was announced on the 18th of November 2019.

"This is an important milestone for Alterity as we advance PBT434 toward patient studies and it follows Orphan Drug designation from the US FDA for treating MSA. It reinforces the dire need for treatment options for this particularly debilitating disease and supports our efforts in preparing for our Phase 2 clinical trial," said Dr David Stamler, Chief Medical Officer and Senior Vice President, Clinical Development.

Last year the company announced Phase 1 clinical trial results. 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 exceeded those associated with efficacy in animal models of MSA and Parkinson's disease (PD).

PBT434 looks to treat Parkinsonian disorders such as MSA and PD. 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.

Authorisation & Additional information
This announcement was authorised by Geoffrey Kempler, CEO and Chairman of Alterity Therapeutics Limited.

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Contact:

Investor Relations
Dylan Mark, WE Communications
E: WE-AUAlterity@we-worldwide.com
Tp: +61 3 8866 1220

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.