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Alterity meets US FDA for ATH434 pathway to treat Multiple System Atrophy

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Alterity Therapeutics announced that it has received guidance from the US Food and Drug Administration (FDA) in relation to the development pathway for ATH434 (previously PBT434), the company's lead compound for the treatment of Multiple System Atrophy (MSA), a Parkinsonian disorder.

The company recently met with the FDA following the successful completion of its Phase 1 clinical trial last year and further data analysis. The pre-IND (Investigational New Drug) meeting was to obtain input on the clinical development plan for ATH434, including feedback on the Phase 2 study design.

Alterity reached an agreement with the FDA on the non-clinical investigations required to support the Phase 2 study. In addition, the FDA agreed to key aspects of the Company's Phase 2 study design including the proposed patient population, safety monitoring plan, and strategy for evaluating drug exposure during the study.

As there are currently no approved treatments for MSA and, therefore, no regulatory precedent regarding accepted efficacy endpoints. FDA has also encouraged Alterity to utilise data from a natural history study that Alterity has planned with clinical and neuroimaging experts at Vanderbilt University Medical Center in the US.

This natural history study, referred to as bioMUSE, or biomarkers of Progression in Multiple System Atrophy, will enrol early-stage MSA patients and track change in clinical parameters and biomarkers for up to one year. Natural history studies are important for characterizing disease progression over time in selected patient populations. Well-conducted, these studies can provide vital information to optimize clinical trial design and inform the selection of biomarkers to evaluate target engagement of drug candidates.

In parallel with the US strategy, Alterity is also pursuing a regulatory pathway in Europe and Australia. Dr David Stamler, Chief Medical Officer, said: "The FDA clearly recognizes the seriousness of MSA and the need for new treatments to address this devastating Orphan disease. Our pre-IND meeting was very collegial, and I look forward to again collaborating with the Division of Neurology to determine the best development path for ATH434 in the US. With the information obtained from this meeting, we have a clear path forward for conducting our Phase 2 study in MSA."