Neurizon Therapeutics Limited
ABN 35 094 006 023
www.neurizon.com

Neurizon Files IND Application to Support HEALEY ALS Platform Trial

Highlights:

- IND application submission to the U.S. Food and Drug Administration (FDA) is a pivotal step in initiating a Phase 2/3 clinical study for NUZ-001
- The IND is a comprehensive dossier of information, including animal and human studies, pharmacokinetic analyses, toxicology studies, and manufacturing information for NUZ-001
- The FDA has a period of 30 days to review the IND application
- NUZ-001 targets TDP-43 protein aggregation, a hallmark of ALS pathology, supported by its demonstrated safety and preliminary efficacy profile in earlier clinical studies

18 December 2024 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company advancing treatments for neurodegenerative diseases, is pleased to announce the filing of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for its lead candidate, NUZ-001. This milestone is a pivotal step in enabling the commencement of a Phase 2/3 clinical trial within the HEALEY ALS Platform Trial framework. The FDA has a period of 30 days to review the IND application.

Dr. Michael Thurn, Managing Director and Chief Executive Officer of Neurizon, commented: "The submission of our IND application to the FDA represents a critical milestone in Neurizon's mission to address the devastating impacts of ALS. The application represents the culmination of several years of research and development and contains many elements that are ultimately required for our New Drug Application (NDA) submission. Our team has worked tirelessly around the clock to produce this foundation regulatory document to realise our goal of commencing the HEALEY ALS Platform Trial. This trial provides an unparalleled opportunity to evaluate the therapeutic potential of NUZ-001 in a collaborative, streamlined manner with the world's leading ALS neurologists. Our team remains committed to advancing this program and delivering hope to patients worldwide who are in urgent need of effective ALS treatments."

About the IND Process

The IND is the mechanism by which the sponsor provides critical information to the FDA to obtain authorization to initiate the safe administration of an investigational agent to humans (or an approved drug used for a new indication or a new population of patients). For the FDA to authorize the use of the investigational agent in humans, the FDA requires sufficient information (animal and any human studies, pharmacokinetic analyses, toxicology studies, and manufacturing information) to assess the safety of the intended human research.

Next Steps

Pending FDA clearance of the IND application, Neurizon anticipates Massachusetts General Hospital (MGH) filing a protocol amendment to their IND for the HEALEY ALS Platform Trial to incorporate our regimen specific appendix in Q1 CY2025. Neurizon expects to initiate patient enrollment in the HEALEY ALS Platform Trial in H1 CY2025.

-ENDS-

This announcement has been authorized for release by the Board of Neurizon Therapeutics Limited.
For further information, please contact:

Dr. Michael Thurn
Managing Director and Chief Executive Officer
Neurizon Therapeutics Limited
enquiries@neurizon.com
+61 (3) 9692 7222

Catherine Strong
Sodali & Co
catherine.strong@sodali.com
+61 (0)406 759 268

About Neurizon Therapeutics Limited

Neurizon Therapeutics Limited (ASX: NUZ) is a clinical-stage biotechnology company dedicated to advancing treatments for neurodegenerative diseases. Neurizon is developing its lead drug candidate, NUZ-001, for the treatment of ALS, which is the most common form of motor neurone disease. Neurizon's strategy is to accelerate access to effective ALS treatments for patients while exploring NUZ-001's potential for broader neurodegenerative applications. Through international collaborations and rigorous clinical programs, Neurizon is dedicated to creating new horizons for patients and families impacted by complex neural disorders.

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