Neurizon Therapeutics Limited
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Neurizon Commences Initiatives to Lift Clinical Hold

Highlights:

- **Ongoing communication with the US FDA regarding Neurizon's IND application for NUZ-001**
- **Formal request for advice detailing two short-term PK studies necessary to lift the clinical hold submitted to the FDA with a formal response expected within 60 days**
- **Neurizon has proactively decided to commence the PK studies required to generate additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001**
- **Studies are low cost and will take around four months from commencement to complete**
- **Decision follows an ongoing review of FDA engagement to date and close collaboration with scientific and regulatory advisors**
- **Initiative highlights the Company's proactive approach to lifting the clinical hold on NUZ-001's IND application to facilitate entry into the HEALEY ALS Platform Trial in H2 CY2025**

17 March 2025 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases, wishes to provide the following update on its ongoing engagement with the United States (US) Food and Drug Administration (FDA), regarding initiatives to lift the clinical hold of the Company's Investigational New Drug (IND) application for NUZ-001.

Neurizon has been in communication with the FDA to seek clarification on the requirements for lifting the clinical hold on NUZ-001 (refer to ASX announcement: 17 February 2025). This has led the company to submit a formal request for advice detailing two short-term, low-cost pharmacokinetic (PK) studies necessary to lift the clinical hold.

These PK studies are anticipated to provide additional animal exposure data specifically requested by the FDA, which will be utilised to assess the adequacy of systemic exposure to NUZ-001 to address the FDA's data request. The FDA has indicated that it will provide a formal response within the next 60 days.

The Company will commence the PK studies in the coming weeks. The studies are expected to take approximately four months from commencement to completion, and includes, study start-up, the 28-day study treatment period, data analysis, and reporting. The initiative is expected to cost between AUD$400,000 to AUD$600,000 and is anticipated to be eligible for rebate under the Australian Government's Research and Development (R&D) Tax Incentive Scheme.

The decision to proactively undertake the additional studies prior to the pending formal response from the FDA follows extensive engagement between the Board, management, and the Company's scientific and regulatory advisors. Additionally, the extra PK data generated from these studies will support the ongoing clinical development of NUZ-001 and future regulatory approval applications.

Managing Director and Chief Executive Officer Dr. Michael Thurn said: "The decision to undertake two pharmacokinetic studies follows the ongoing review of our correspondences with the FDA to date, as well as close consultation with the Company's scientific and regulatory advisors. The two studies, which are anticipated to be completed in around four months, are expected to generate additional animal exposure data in line with the FDA's straightforward request to date to lift the clinical hold.

"Undertaking these studies prior to the receipt of a formal response from the FDA highlights the Company's proactive approach to satisfying the regulator's request and our ongoing commitment to advancing NUZ-001 as an effective potential treatment for ALS and other neurodegenerative diseases. The timely execution of these studies will allow NUZ-001 entry into the HEALEY ALS Platform Trial during the second half of CY2025. We look forward to providing further updates to shareholders on the commencement of these studies."

-ENDS-

This announcement has been authorized for release by the Board of Neurizon Therapeutics Limited.

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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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