Neurizon Therapeutics Limited
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FDA Provides Positive Feedback on Strategy to Lift Clinical Hold for NUZ-001

Highlights:

- **FDA has provided positive written feedback on Neurizon®'s strategy to resolve the clinical hold for NUZ-001**
- **The two preclinical pharmacokinetic studies requested have been completed ahead of schedule, and the study reports are being finalised**
- **Neurizon anticipates submitting the Complete Response in the coming weeks, requesting the FDA to lift the clinical hold**
- **Company remains committed and well placed to participate in the HEALEY ALS Platform Trial in Q4 CY2025**

10 July 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, is pleased to announce progress across key clinical and regulatory activities for its lead program, NUZ-001, for the treatment of amyotrophic lateral sclerosis (ALS).

Following recent formal interactions, the U.S. Food and Drug Administration (FDA) has provided written feedback confirming procedural alignment with Neurizon's strategy to lift the clinical hold for NUZ-001. This regulatory feedback outlines the FDA's acceptance of Neurizon's strategy of conducting two preclinical pharmacokinetic (PK) studies to address the clinical hold for NUZ-001, enabling continued momentum towards initiating the HEALEY ALS Platform Trial.

Neurizon has already completed the two necessary PK studies ahead of schedule. These studies were conducted by a global contract research organisation (CRO) specialising in preclinical PK studies. The treatment phase of both studies has been successfully completed, along with the analysis of blood samples, and the study reports are being finalised. The execution of these studies was completed within budget and may qualify for a rebate under the Australian Government's Research and Development (R&D) Tax Incentive Scheme.

Neurizon anticipates submitting a Complete Response containing data from these PK studies to the FDA in the coming weeks as part of the formal hold resolution process. The Company remains focused on activating participation in the HEALEY ALS Platform Trial in Q4 CY2025.

Managing Director and Chief Executive Officer, Dr Michael Thurn, commented: "We are delighted to receive written confirmation from the FDA affirming our strategy to resolve the clinical hold for NUZ-001. By proactively progressing and completing the required PK studies ahead of schedule, we've maintained strong momentum and demonstrated our commitment to advancing NUZ-001 with urgency and scientific precision. We are well-positioned to submit the Complete Response in the coming weeks and anticipate that the clinical hold will be lifted in August 2025. We are focused on achieving key milestones that will enable Neurizon's active participation in the HEALEY ALS Platform Trial later this year."

The Company will continue to update the market as key regulatory and clinical milestones are achieved in the lead-up to anticipated trial participation in Q4 CY2025.

-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 the potential of NUZ-001 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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