Neurizon Therapeutics Limited
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FDA Lifts Clinical Hold on NUZ-001

Highlights:

- **U.S. FDA lifts the Clinical Hold on NUZ-001, Neurizon®'s lead investigational therapy for ALS**
- **Clears the way for entry into the HEALEY ALS Platform Trial expected to commence in Q4 CY2025**
- **IND supported by robust preclinical safety data and comprehensive manufacturing and quality information from the previously signed Elanco licensing agreement**
- **Expedites NUZ-001 as a platform molecule with pipeline expansion potential**
- **Positions Neurizon for accelerated regulatory pathways and future partnering opportunities**

6 October 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 that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on its lead investigational drug, NUZ-001. This decision marks a pivotal regulatory milestone for Neurizon and the ALS community, clearing the way for Phase 2/3 development of NUZ-001 as part of the HEALEY ALS Platform Trial, expected to commence Q4 CY2025.

Dr Michael Thurn, Managing Director and CEO, commented: "The FDA's clearance of our IND application marks a significant milestone in our mission to bring NUZ-001 closer to patients living with ALS. This achievement reflects both our unwavering commitment to rigorous scientific and clinical development and the tireless dedication of our team.

We are deeply grateful to the key opinion leaders (KOLs) and patient advocacy groups whose steadfast support and engagement were instrumental in shaping and advancing this program. Their efforts in raising awareness and lobbying for the urgent needs of the ALS community have been invaluable in helping us reach this point.

We are now partnering with the HEALEY ALS Platform Trial team to take the next critical steps in advancing NUZ-001. Supported by our compelling TDP-43 preclinical data and encouraging survival outcomes from the Open-Label Extension (OLE) study in ALS patients, we believe NUZ-001 has the potential to meaningfully slow the progression of this devastating disease."

Opening an IND for a platform molecule establishes a regulatory foundation that not only accelerates the development of the first candidate but also streamlines future programs. By creating a validated framework for safety, manufacturing, and clinical design, it reduces regulatory risk, shortens timelines, and enables efficient expansion into new indications.

In this case, the IND is further strengthened by the robust and comprehensive package of preclinical safety data and the detailed manufacturing and quality information secured through our licensing agreement with Elanco. These resources enhance confidence in the platform's readiness for clinical development and reinforce its potential as a therapeutic platform with broad applicability, offering both strategic flexibility and long-term commercial value.

Next Steps:

With IND now active, Neurizon anticipates Mass General Hospital (MGH) filing a protocol amendment to their IND for the HEALEY ALS Platform Trial to incorporate our specific protocol regimen early in the coming weeks. Neurizon expects to initiate patient enrollment in the HEALEY ALS Platform Trial in Q4 CY2025.

Together, these milestones advance Neurizon's mission to accelerate patient access to innovative therapies, create long-term value for shareholders, and establish NUZ-001 as a potential effective treatment for ALS.

-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. NUZ-001 is an investigational product and is not approved for commercial use in any jurisdiction.

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