Neurizon Therapeutics Limited
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NIH funds Expanded Access Program for NUZ-001 in ALS

Highlights:

- **US National Institutes of Health ("NIH") awards a multimillion-dollar, multiyear grant to fund an Expanded Access Protocol (EAP) for NUZ-001 (NIH Project Number 1U01NS153995-01)**
- **Program expected to provide up to 200 people living with ALS who are otherwise ineligible for clinical trials with access to NUZ-001 for up to 96 weeks**
- **EAP is fully funded through the NIH award, including Neurizon's drug supply and regulatory costs**
- **Sean M. Healey & AMG Center for ALS will be the prime recipient of the NIH grant, with Neurizon receiving funding as subawardee**
- **Neurizon will serve as regulatory sponsor and IND holder and will supply NUZ-001, with the Healey & AMG Center responsible for clinical and operational execution of the EAP**
- **Program will broaden clinical exposure to NUZ-001 and generate complementary long-term safety, biomarker, survival and clinical data**
- **Data collection will run alongside the ongoing Phase 2/3 HEALEY ALS Platform Trial, with the EAP's continuation beyond topline results (expected late Q2 CY27) contingent on a positive trial outcome**
- **~20 physical clinical sites participating in the HEALEY ALS Platform Trial and a national virtual site are planned, providing potential access across 50 US states**
- **EAP start-up activities underway, with participant enrolment targeted to commence by Q1 CY27**

09 September 2026 – Melbourne Australia: Neurizon® Therapeutics Limited (ASX: NUZ; OTCQB: NUZTF) (Neurizon or the Company), a late clinical-stage biotechnology company dedicated to advancing innovative treatments for neurodegenerative diseases, is pleased to advise that the Sean M. Healey & AMG Center for ALS at Mass General Brigham (Healey & AMG Center) has been awarded a multimillion-dollar, multi-year grant from the US National Institutes of Health ("NIH") to conduct an Expanded Access Protocol (EAP) with Neurizon's lead investigational therapy, NUZ-001, in people living with amyotrophic lateral sclerosis ("ALS").

The NIH-funded EAP is expected to provide up to 200 people living with ALS who are otherwise ineligible to participate in clinical trials with access to NUZ-001 for up to 96 weeks. The program will run in parallel with Regimen I of the Phase 2/3 HEALEY ALS Platform Trial, where NUZ-001 is currently being evaluated in approximately 250 participants. The EAP will continue beyond the topline results, expected in late Q2 CY2027**,** contingent on a positive trial outcome.

Expanded Access, also referred to as Compassionate Use, provides a pathway for people with serious or life-threatening diseases to access an investigational therapy that has not yet been approved by the US Food and Drug Administration ("FDA") where participation in an appropriate clinical trial is not available.

The EAP is designed to generate long-term real-world data from a broader ALS population than is typically represented in randomised clinical trials. The program will collect safety and tolerability data together with survival, ALS-specific functional and respiratory measures (including ALSFRS-R and slow vital capacity), patient-reported outcomes and exploratory biomarkers.

Data generated through the EAP will be complementary to the controlled efficacy and safety data being generated from Neurizon's participation in the Phase 2/3 HEALEY ALS Platform Trial. The program is expected to significantly expand the long-term safety database for NUZ-001 and provide additional survival, biomarker and clinical data to inform its ongoing clinical development.

The program is expected to be conducted through ~20 physical ALS clinical trial sites and a national virtual study site, providing potential access across 50 US states. The physical sites will include sites already participating in the HEALEY ALS Platform Trial, while the virtual model is designed to facilitate participation for people living with ALS who may otherwise have difficulty accessing clinical research, including those in rural and underserved areas.

The Healey & AMG Center will lead the clinical and operational execution of the EAP, including site activation, participant recruitment and data collection. Neurizon will serve as regulatory sponsor with the EAP conducted under Neurizon's IND, and will be responsible for supplying NUZ-001.

The EAP is fully funded through the NIH award, which provides for EAP-related drug supply, manufacturing and specified regulatory, safety monitoring and operational costs associated with Neurizon's participation. Neurizon is

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well positioned to support the additional clinical demand for NUZ-001 through its existing drug supply and long-term supply agreement with Elanco Animal Health Incorporated (Elanco), which provides the Company with access to scalable supplies of active pharmaceutical ingredient for NUZ-001. The grant application provides for API supply, drug product manufacturing, shipment and regulatory and pharmacovigilance activities within the program budget.

Interim Executive Chairman, Sergio Duchini said: "Neurizon is proud to support the Healey & AMG Center in this important initiative, which will provide up to 200 people living with ALS who are otherwise ineligible to participate in clinical trials with access NUZ-001 for up to 96 weeks. The EAP will also significantly expand our long-term safety database and generate valuable biomarker, survival and real-world clinical data from a broader ALS population.

"The program will run in parallel with Regimen I of the HEALEY ALS Platform Trial and complements the rigorous controlled evidence being generated through that study. Together, these programs will broaden our understanding of NUZ-001 and provide complementary data that may further inform its clinical development.

"We are grateful to the NIH and the Healey & AMG Center team for their leadership and, particularly, to people living with ALS and their families whose participation continues to advance the search for more effective treatments."

Dr Sabrina Paganoni, Healey & AMG Center, commented: "Expanded Access Programs provide an important opportunity for people living with ALS who are not otherwise eligible for clinical trials to access investigational products. We are grateful to the NIH for supporting this effort and for helping advance opportunities for research in ALS."

Next Steps:

EAP start-up activities are currently underway. Subject to completion of the required regulatory, site activation and operational processes, participant enrolment is targeted to commence by Q1 CY27. The EAP will be available to eligible people living with ALS in the US. Further details regarding participating sites, eligibility criteria and enrolment will be provided by the Healey & AMG Center as the program progresses.

-ENDS-

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

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About Neurizon Therapeutics Limited

Neurizon Therapeutics Limited (ASX: NUZ) is a late 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 program, 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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