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

# Neurizon Therapeutics Receives Positive Opinion on Orphan Medicinal Product Designation for NUZ-001 in Europe

**Highlights:**

- **Notice of positive opinion received from the European Medicines Agency for Orphan Medicinal Product Designation for NUZ-001 in Amyotrophic Lateral Sclerosis**
- **Orphan Designation offers 10 years of market exclusivity in Europe upon product approval, along with additional regulatory and commercial benefits**
- **Positions Neurizon to advance the development of NUZ-001 for patients facing ALS, a debilitating neurodegenerative disease with limited treatment options**

**11 November 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 it has received notice of a positive opinion from the European Medicines Agency (EMA) for Orphan Medicinal Product Designation (OMPD) following its application for its lead drug candidate, NUZ-001, for the treatment of Amyotrophic Lateral Sclerosis (ALS). The European Commission is scheduled to issue the official decision on the Orphan Designation in December.

OMPD will offer Neurizon a range of attractive incentives for NUZ-001. These include reduced regulatory fees, free protocol assistance, and, importantly, 10 years of market exclusivity in the European Union (EU). During the exclusivity period, the EMA and the EU Member States will not accept another marketing authorisation application for a similar medicinal product in the same therapeutic indication.

Neurizon is advancing NUZ-001 through a Phase 2/3 clinical study as part of the HEALEY ALS Platform Trial, with patient enrolment expected to commence in early H1 CY2025. Our protocol regimen has been designed to support the potential for early regulatory approval. The notice of a positive opinion from the EMA on the OMPD further supports our pathway for NUZ-001, underscoring its potential to meet urgent unmet needs in ALS on a global scale.

**Managing Director and Chief Executive Officer, Dr Michael Thurn commented**: "Receiving a positive opinion from the EMA for Orphan Medicinal Product Designation is a critical milestone for Neurizon. The prevalence in the EU is double that of the United States.[1] With the OMPD, along with the Orphan Drug Designation from the United States Food and Drug Administration, we have secured market exclusivity for NUZ-001 across the world's key markets for the treatment of ALS. This important recognition highlights the significant potential of NUZ-001 to provide a meaningful therapeutic option for patients with ALS while building the commercial value of this promising candidate. We look forward to further engagement with the EMA and other regulators as we advance our mission to deliver innovative treatments to patients battling this devastating disease."

**Next Steps:**

- A formal decision from the European Commission is scheduled for December 2024.
- Continue regulatory engagement with the EMA and the United States Food and Drug Administration to support the clinical development pathway of NUZ-001.
- Finalise preparations for the Phase 2/3 clinical study through the prestigious HEALEY ALS Platform Trial, in alignment with the Company's strategic focus on neurodegenerative diseases.

-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.

[1] Park J, Kim J-E and Song T-J (2022) The Global Burden of Motor Neuron Disease: An Analysis of the 2019 Global Burden of Disease Study. *Front. Neurol.* 13:864339. doi: 10.3389/fneur.2022.864339

## Neurizon Investor Hub

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning Neurizon.
This platform offers anopportunity to submit questions, share comments, and view video summaries of key announcements.

To access Neurizon Investor Hub please scan the QR code or visit
https://investorhub.neurizon.com

Neurizon
Investor Hub