

US Patent granted for NUZ-001 for the treatment of Neurodegenerative Diseases

Highlights:

- Patent granted by the USPTO covering the use of Neurizon's lead drug candidate, NUZ-001, in neurodegenerative diseases and cancer
- Granted patent provides specific protection for NUZ-001 and structurally related compounds used in treatments for mTOR pathway-related diseases in the US market until 2039
- Considerably strengthen Neurizon's commercial potential and provides a strong framework for any future licensing negotiations
- Patent grant follows FDA Orphan Drug Designation (ODD) for NUZ-001 in May 2024, further enhancing the Company's IP estate and market position for NUZ-001 as the clinical trial pipeline advances

5 February 2025 – Melbourne, Australia: Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing treatments for neurodegenerative diseases, is pleased to confirm it has received an Issue Notification from the United States Patent & Trademark Office (USPTO) informing the grant of a 'method of use' patent in connection with its lead amyotrophic lateral sclerosis/motor neurone disease (ALS/MND) drug candidate, NUZ-001.

In December 2023, Neurizon was granted an expedited review by the USPTO after submitting a petition to make special (PTMS). The granted patent pertains to a Neurizon-owned IP covering the 'method of use' of NUZ-001 in effective doses to treat mTOR pathway-related diseases, including ALS/MND, along with multiple forms of other neurodegenerative diseases, in particular Alzheimer's disease, Huntington's disease and Parkinson's disease, and cancer. The patent protection runway for NUZ-001 and structurally related compounds for neurodegenerative diseases and cancer in the US now extends to 2039.

It follows the receipt by Neurizon of Orphan Drug Designation (ODD) status from the United States (US) Food and Drug Administration (FDA) for its NUZ-001 treatment in May 2024 (*refer ASX Announcement 17 May 2024*). Along with the ODD designation, the grant of this patent strengthens the development, commercialisation potential and market opportunity for NUZ-001 by providing protection against generic competition in the US.

The US patent was issued on 4 February 2025, with patent number 12,213,957.

Managing Director and Chief Executive Officer, Dr Michael Thurn said: "We are pleased to confirm the expedited grant of this important patent in the US. This comes at a critical juncture for the Company, as we ramp up our product commercialisation strategy in the US. We are confident that obtaining this US patent protection significantly strengthens our market positioning and provides a strong framework for future licensing negotiations. The patent application is still under review in all other major regulatory jurisdictions worldwide. We look forward to reporting additional grants in the near future."

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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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