Neurizon Therapeutics Limited
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FDA Guidance on NUZ-001 IND Application

Highlights:

- **FDA has provided further clarification on Neurizon's IND application for NUZ-001**
- **FDA has responded with only one straightforward request for additional information**
- **Neurizon to provide additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001 in previous studies**
- **The impact of the FDA's request on the timeline of the Company's planned ALS clinical trial is currently being assessed**
- **FDA did not specify any safety concerns arising from previously undertaken clinical studies utilising NUZ-001**

17th February 2025 – Melbourne, Australia: Further to its announcement to ASX on 17 January 2025, Neurizon Therapeutics Limited (ASX: NUZ & NUZOA) ("Neurizon" or "the Company"), a clinical-stage biotech company dedicated to advancing innovative treatments for neurodegenerative diseases, received guidance from the United States (U.S.) Food and Drug Administration (FDA) on Saturday, 15 February 2025, regarding the FDA placing the Company's Investigational New Drug (IND) application for NUZ-001 under clinical hold.

As anticipated in the Company's prior announcement, the FDA has now provided further clarification. Following review, the FDA has requested additional animal exposure data be provided for the FDA to assess the adequacy of systemic exposure to NUZ-001 during the relevant studies that have been undertaken. The Company has commenced initiatives to generate the additional exposure data and remains confident that further information will assist in reinforcing and better defining safety margins for NUZ-001's clinical development program. Pleasingly, the FDA did not specify any safety concerns arising from previously undertaken clinical studies utilising NUZ-001.

Managing Director and Chief Executive Officer Dr. Michael Thurn said: "We appreciate the FDA's guidance and are pleased that the FDA has responded with only one straightforward request for additional information. This request focuses on enhancing and ensuring confidence in the previous animal safety data generated for NUZ-001 used in veterinary applications.

Neurizon considers that it is well-positioned to meet the FDA's additional request. With established regulatory and scientific expertise, strong industry partnerships, and an open and constructive relationship with the FDA, we will work swiftly to generate the requested information to further strengthen the regulatory package for NUZ-001's clinical development. We remain committed to advancing NUZ-001 as an effective potential treatment for ALS and other neurodegenerative diseases."

The Company has commenced planning the necessary steps to address the FDA's request. Neurizon's Board, management, scientific, and regulatory teams are working to expeditiously advance this process, leveraging its established expertise and strong industry partnerships. The impact of the FDA's request on the timeline of the Company's planned ALS clinical trial is currently being assessed. Neurizon is continuing to work through the FDA's request and will provide further updates to shareholders as developments materialise.

-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 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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