

## PHARMAUST GRANTED SME STATUS BY EUROPEAN MEDICINES AGENCY

### Highlights:

- The European Regulatory Agency has granted PharmAust small and medium-sized enterprise (SME) status
- PharmAust is entitled to a range of financial benefits, including reductions in fees for scientific advice, inspections, and pre- and post-marketing authorisation applications
- The incidence of MND/ALS in European countries are amongst the highest globally
- There is only one drug, riluzole, that treats all types of MND/ALS in Europe prolonging life by only 2-3 months

**1 July 2024 – Melbourne Australia:** PharmAust Limited (ASX:PAA) (**PharmAust** or the **Company**), a clinical-stage biotechnology company, is pleased to announce it has been granted small and medium-sized enterprise (SME) status by the European Medicines Agency (EMA). This status entitles PharmAust to receive regulatory fee incentives and additional support from the EMA, streamlining regulatory engagement and the Company's ability to advance monepantel for the treatment of motor neurone disease (MND)/ Amyotrophic Lateral Sclerosis (ALS).

The SME status provides eligible companies with a range of financial benefits, including reductions in fees for scientific advice, inspections, and pre- and post-marketing authorisation applications. It is available to eligible enterprises with fewer than 250 employees and not more than €50 million in revenue. Further details are available on the European Medicines Agency's website: [Financial advantages of SME status | European Medicines Agency](#).

### **PharmAust Managing Director Dr Michael Thurn commented:**

"We are proud to receive SME status from the EMA. This signals the beginning of a productive partnership with the key drug regulator in Europe and an important step towards accelerating start-up activities for our adaptive Phase 2/3 Strike study. The incidence of MND/ALS in European countries are amongst the highest globally, ranging from 1.5 to 3.8 per 100,000 people.<sup>1</sup> Incredibly, there is only one drug, riluzole, approved for the treatment of all types of MND/ALS in Europe which only offers patients an additional 2-3 months in life expectancy. The SME status from the EMA provides continued momentum in our efforts to help patients and their families impacted by MND/ALS."

This announcement is authorised for release by the Board of Directors of PharmAust Limited.

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## About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (ASX Code: PAA). PAA is a clinical-stage biotechnology company developing therapeutics for neurodegenerative diseases. The company is focused on repurposing monepantel (MPL) for amyotrophic lateral sclerosis (ALS). ALS is the most common form of motor neurone disease (MND) and affects both upper and lower motor neurons.

MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in the growth and proliferation of cancer cells and degenerating neurons. The mTOR pathway regulates the cellular “cleaning process”, where toxic proteins are broken down into macromolecules to be reused. This autophagic process is disrupted in most neurodegenerative diseases, including ALS.

The company recently announced positive top-line results for its Phase 1 MEND study in participants with ALS. PAA is in the planning stages for a registration adaptive Phase 2/3 STRIKE clinical study and anticipates commencing enrolment in H2 CY 2024. This single pivotal study could potentially lead to accelerated approval with the US Food and Drug Administration for monepantel for the treatment of ALS in 2026.

In 2024, the Neurodegenerative Disease Market size is estimated to be worth USD 55.12 billion, with a forecast growth (CAGR) of 7.14% the market size is expected to reach USD 77.82 billion by 2029.<sup>2</sup>

<sup>1</sup> Barceló, M.A., Povedano, M., Vázquez-Costa, J.F. et al. Estimation of the prevalence and incidence of motor neuron diseases in two Spanish regions: Catalonia and Valencia. *Sci Rep* 11, 6207 (2021). <https://doi.org/10.1038/s41598-021-85395-z>

<sup>2</sup> <https://www.mordorintelligence.com/industry-reports/neurodegenerative-disease-market>

## PharmAust Investor Hub:

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

Access the investor hub by scanning the QR code or visiting: <https://investorhub.pharmaust.com/>

