FightMND Invites PharmAust to Apply for Phase 2/3 Grant Funding

Highlights:

- **PharmAust has been invited by FightMND to submit a full grant application to help fund its Phase 2/3 Clinical Study**
- **Up to AUD $1,800,000 in support from FightMND is available per grant**
- **Applications are due by the 24th of March 2024 and successful recipients will be notified in July 2024**
- **PharmAust's planned Phase 2/3 study is a multicentre, randomised, placebo-controlled, adaptive clinical study evaluating the safety and efficacy of monepantel in patients with MND/ALS over 48 weeks**

22 December 2023 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAOA) ("PharmAust" or "the Company"), a clinical-stage biotechnology company, is pleased to announce that FightMND, Australia's leading not-for-profit foundation for Motor Neurone Disease Research has invited PharmAust to submit a full grant application to help cover costs of its planned Phase 2 study due to begin in H1 2024.

Early this month PharmAust submitted a Letter of Intent to FightMND in response to their call for clinical study proposals as part of their Phase 2/3 clinical trial and expanded access program for novel, high-potential treatments in Motor Neurone Disease/Amyotrophic Lateral Sclerosis (MND/ALS) within the Australian Clinical Trials Consortium of hospitals. Associate Professor Susan Mathers will be the principal investigator.

The call for clinical study proposals is intended for academic-industry partnerships including but not limited to pharmaceutical, bio-therapeutic/ biotechnology companies, academic institutions and universities, hospitals, and MND researchers throughout the world. Up to AUD $1,800,000 in support from FightMND is available per grant.

PharmAust has been notified by FightMND that its Letter of Intent was successful and invited PharmAust to submit a full application by the 24th of March 2024. Successful recipients will be notified in July 2024.

PharmAust's planned Phase 2/3 study is a multicentre, randomised, placebo-controlled, adaptive clinical study evaluating the safety and efficacy of monepantel (MPL) in patients with MND/ALS over 48 weeks. The primary aim will be to evaluate the efficacy of MPL, as compared to placebo, on MND/ALS disease progression. This will be assessed as change from baseline in disease severity as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R) total score and survival. As this is an adaptive study design, an interim analysis will be performed at Week 24 by a team of unblinded statisticians for the potential to stop the study early for either success or futility.

PharmAust Chief Executive Officer Dr Michael Thurn commented:
"Gaining access to undiluted funds to help offset the costs of drug development is a goal of every biotechnology company. FightMND has already been influential to date in the development of monepantel for MND/ALS by fully funding our initial Phase 1 study. Based on the potential shown to date for monepantel to provide patients with MND/ALS with a treatment benefit were are excited at our prospects of securing further funding from FightMND for our adaptive Phase 2/3 study."

The Board authorises this announcement.

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About Motor Neurone Disease:

According to the International Alliance of ALS/MND Associations, MND affects over 350,000 people globally and kills more than 100,000 people yearly. The disease is invariably fatal, with the average life expectancy of someone with MND being around 27 months. The MND/ALS addressable market is US$3.6Bn per annum, with the standard of care treatment, Riluzole, only prolonging life on average by 2-3 months.

The disease is progressive, meaning the symptoms get worse over time. MND has no cure and no effective treatment to reverse its progression. Independent studies have shown that one-third of patients die within 12 months after the first diagnosis.

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 human and animal health applications. The company is focused on repurposing monepantel (MPL) for human neurodegenerative diseases and treating cancer in dogs.

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

PAA’s lead MPL program is for the treatment of MND/ALS, a rare, incurable disease. The company is currently completing a Phase 1 study in patients with MND/ALS. Top-line results are expected to be announced in Q1 CY2024. PAA anticipates starting a Phase 2 study in H1 2024 that could lead to accelerated approval with the US Food and Drug Administration in 2026. PAA is preparing to start a pivotal field trial in dogs with B-Cell Lymphoma to enable product registration in the US in 2025. PAA has previously successfully completed a Phase 1 oncology clinical study of monepantel in humans and pilot studies in canine cancer.