



Pitney Pharmaceuticals
Pty Limited



First Patient Dosed in Motor Neurone Disease Phase 1/2 Trial

- Clinical Study Protocol minor amendments to speed recruitment
- Additional patients currently undergoing screening

3 October 2022 – Perth, Australia: PharmAust Limited (ASX:PAA & PAAO), a clinical-stage biotechnology company, is pleased to report the first patient has been dosed in its Phase 1/2 Trial testing the effects of monepantel (MPL) in individuals living with motor neurone disease (MND).

Also ethics approval has been granted to make a few small amendments to the Clinical Study Protocol to refine the study design and accelerate recruitment.

The trial is testing the safety and tolerability of MPL in patients living with MND. It will also look for signs that MPL can slow the progression of MND. This data, with concurrent animal studies, will determine whether MPL should proceed to larger Phase 2 studies.

PharmAust previously announced it received a funding commitment of A\$881,085 for a Phase 1/2 trial examining the effects of MPL in MND, otherwise known as Lou Gehrig's disease or Amyotrophic Lateral Sclerosis (ALS). These funds were granted by FightMND, the largest independent funder of MND research in Australia. The trial is overseen by Dr Susan Mathers of Calvary Health Care, Bethlehem, Melbourne and will include a second trial site headed by Professor Dominic Rowe of the Centre for Motor Neurone Disease Research Faculty of Medicine and Health Research at Macquarie University, Sydney.

The funding agreement provides that PharmAust shall own all intellectual property generated from the trial.

The third instalment of \$173,034.80 is now payable upon recruitment of the first patient. Further instalments for a total of \$881,085 will be paid by FightMND to PharmAust as clinical trial milestones are met.

This announcement is authorised by the Board

Enquiries:

Dr Roger Aston
Executive Chairman
rogeraston@pharmaust.com

P +61 (8) 9202 6814
F +61 (8) 9467 6111
W www.pharmaust.com

About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company which generated \$3.4 million in sales of goods & services in FY 2022.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

About FightMND

Founded in 2014, FightMND was established in Australia with the purpose of finding effective treatments and ultimately a cure for Motor Neuron Disease (MND), also referred to as ALS or Lou Gehrig's Disease. FightMND, with its vision of a world without MND, is the largest independent funder of MND research in Australia. Since 2014, FightMND has investment more than \$63 million into MND research and care equipment to improve the lives of those fighting the disease. FightMND is determined to help facilitate the translation of the growing body of new knowledge about the disease into a cure for MND patients in Australia and abroad. For more information about FightMND, visit the website at <https://fightmnd.org.au>.