



Pitney Pharmaceuticals  
Pty Limited

## PharmAust completes MPL demonstration batch manufacture; reaches out to COVID-19 trial sites

- PharmAust completes demonstration 500g batch MPL
- Purity greater than previous GMP batches
- MPL demonstration batch arrives in the US for smaller tablet design
- MPL GMP manufacturing has commenced.
- Further to the Company's preclinical studies on COVID-19, PharmAust reaches out to Contract Research Organisations (CRO) to identify sites for the evaluation of MPL in COVID-19 patients
- PharmAust in final stages of negotiations with CROs for FightMND-supported clinical trial oversight.

**21 October 2021 – Perth, Australia:** PharmAust Limited (ASX:PAA), a clinical-stage biotechnology company, is pleased to provide an update on its manufacturing programs for the use of MPL in COVID-19 and FightMND-funded MND clinical trials.

PharmAust can report that the 500g demonstration batch of MPL generated demonstrates a greater purity profile than the previous GMP batches used in the Phase 1 trial in humans and the Phase 2a and 2b trials in pet dogs with B cell lymphoma. The demonstration batch has now arrived in the US for the preparation of the new smaller tablet design for use in the MND and COVID-19 trials in humans.

Success in the manufacture of this demonstration batch means that PharmAust is now in the process of scaling up a GMP batch ready for the FightMND and COVID-19 trials to commence around April 2022. PharmAust is in final negotiations with organisations that will provide the necessary MND trial services: clinical oversight, regulatory oversight, monitoring, pharmacokinetic analysis and pharmacodynamic analysis. Further to PharmAust's preclinical program on the effects of MPL on SARS-CoV-2 virus infection and replication, we are now able to confidently commence negotiations with CROs to identify trial sites for testing MPL in people infected with the virus causing COVID-19.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "Despite the delays incurred in manufacture due to the global COVID-19 pandemic, PharmAust remains on track to recommence clinical trials in humans with a newly designed tablet, suitable for dosing regimens in people with Covid-19 and motor neurone disease."

This announcement is authorised by the Board

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### **About PharmAust (PAA):**

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 that generated \$2.2 million in revenue in FY 2021.

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>.