



Pitney Pharmaceuticals
Pty Limited



Arrival of additional MPL tablets

- **Approximately 10,000 cGMP MPL tablets received**
- **Ensures continued availability of MPL tablets for the Phase 1/2 MND trial and maintenance dosage**
- **Sufficient tablets to commence other human clinical trials**

17 April 2023 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to announce the arrival of additional cGMP (current Good Manufacturing Practice) grade monepantel (MPL) tablets.

Pre-release technical specifications of the cGMP MPL tablets demonstrate that the formulation, purity and stability specification required have been achieved.

The receipt of approximately 10,000 tablets will ensure continued availability of MPL tablets for the Phase 1/2 MND trial and ongoing maintenance dosage.

PharmAust notes that, thus far, all patients have elected to remain on MPL post Day 29 and wish to continue receiving PharmAust's MPL tablets. Continuation of access and treatment with Investigational Product is a permitted option in the protocol.

The additional tablets are also sufficient to commence one or more other human clinical trials.

GMP tablet manufacture is a key component for undertaking GCP (Good Clinical Practice) trials and will enable the data emerging from forthcoming trials to be admissible to the U.S. FDA to support new drug registration programs. Furthermore, adoption of GMP standards ensures products meet the highest standards of safety and efficacy.

The MPL tablets were manufactured in collaboration with Syngene International Ltd., an integrated research, development and manufacturing services company and Catalent Pharma Solutions (NYSE: CTLT) who performed the production of the cGMP-grade MPL tablets suitable for use in the upcoming human trials.

The tablets will be stored in the stability chamber at wholly owned subsidiary, Epichem Pty Ltd in Perth.

The Board has authorised this announcement.

Anusha Aubert
Investor Relations
investorenquiries@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 (PAA) and the Frankfurt Stock Exchange (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 \$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 showed objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treating human and veterinary cancers and neurodegenerative diseases as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

