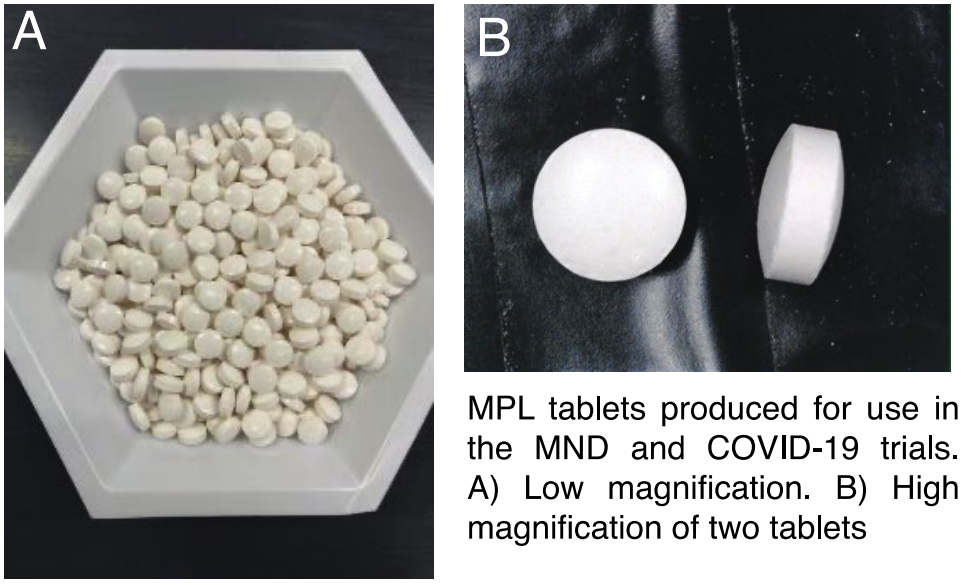
Demonstration batch of smaller size MPL tablets completed

- Smaller size non-GMP monepantel tablet batch manufacturing successfully completed
- Smaller size tablets for motor neuron disease (MND) and COVID-19 have a lower monepantel dose per tablet than those for cancer
- Stability studies to support early starts for the MND and COVID-19 clinical trials are underway
- GMP tablet manufacturing scheduled for February 2022

1 December 2021 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, confirms that non-GMP batch testing of smaller size monepantel tablets for the upcoming MND and COVID-19 clinical trials is completed.

A total of 2,000 demonstration batch tablets were successfully produced using the same process used to produce the previous larger tablets for anti-cancer applications. Particle size, bulk density and solid fraction remain similar, meaning that GMP tablet manufacture can now commence with confidence following the scheduled January 2022 delivery of GMP grade monepantel.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "It is a great outcome to convert from large to small dose tablets so quickly. The smaller dose tablets were also shape-modified to facilitate swallowing for individuals with motor neuron disease. Having the stability set up for the demonstration batch now means that PharmAust is looking forward to having three month accelerated stability studies completed in time to support an early start to the clinical trials once the GMP tablet batch is finalised."



MPL tablets produced for use in the MND and COVID-19 trials. A) Low magnification. B) High magnification of two tablets

GMP: good manufacturing process

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.