Update on Manufacture of Monepantel (API) and Tablets for Clinical Trials

2 February 2022 – Perth, Australia: PharmAust Limited (ASX:PAA & PAAO), a clinical-stage biotechnology company, provides this update on its manufacturing program for the active pharmaceutical ingredient (API) and the formulation and preparation of tablets for clinical trials in humans.

Following feedback from its manufacturing partners PharmAust is on schedule to meet the nominated clinical trial deadlines with the first patient due to be recruited for the Phase I/II human trial in motor neurone disease (MND) by the end of May 2022.

Monepantel manufacturing is scheduled for completion mid-February 2022. The API product will then be shipped to the US for formulation and tableting. Tabletting is scheduled for completion mid-March 2022. Implementation of a successful accelerated stability program mid-April should enable the release of finished product in May 2022.

Throughout the manufacturing and development process PharmAust has focussed on developing a high purity specification for the product, suitable for both human and veterinary purposes. The Company has also created a unique manufacturing process to optimise yields, purity and shelf-life stability.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "Late May 2022 remains the scheduled timing for recruitment of the first person into the MND clinical trial. We will then follow this up with recruiting for a COVID-19 antiviral clinical trial. We are looking forward to a year of working through many milestones."

Protocols and ethics/regulatory approvals are now in place for the evaluation of monepantel in motor neurone disease. The trial will test safety and tolerability in patients living with MND and look for signs that monepantel can slow its progression.

This announcement is authorised by the Board

Enquiries:

Dr Roger Aston
Executive Chairman
rogeraston@pharmaust.com

Dr Richard Mollard
Chief Scientific Officer
rmollard@pharmaust.com

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

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.