Independent tests show MPL retains long-term shelf-life and product stability

- Ongoing stability data for monepantel shows at least 12-month tablet shelf-life with specifications remaining well within limitations for human use
- Product stability and shelf-life are important as PharmAust moves toward Phase 2 human trials and identifies potential commercial partners
- $118,926.80 milestone payment is now payable by FightMND

10 May 2023 – Perth, Australia: PharmAust Limited (ASX:PAA & PAAO), a clinical-stage biotechnology company, is pleased to report that, after formally testing monepantel tablets for 12 months in storage at a controlled temperature of 25°C with 60% humidity, the tablets remain within specifications relevant for human clinical trials.

The Good Manufacturing Practice (GMP) grade stability study conducted independently by Catalent Pharma Solutions (NYSE: CTLT) was for a storage period of at least 12 months. GMP is a globally recognised standard which requires rigorous, controlled and documented processes to provide fully-characterised drugs with the highest levels of purity for safe and effective administration to patients.

GMP meets the standards required for clinical trials in Australia, the United States and Europe.

The next FightMND grant instalment of $118,926.80 is now payable to PharmAust after the completion of this 12-month GMP Stability Study. A further $138,134.80 will be payable upon the completion of Cohort 3 (expected around next month) and $150,142.80 will be payable upon the completion of Cohort 4 (expected around July 2023).

PharmAust Executive Chairman, Dr Roger Aston stated, “We are delighted with the latest stability achievements in the development of monepantel. Having a robust GMP tablet significantly reduces costs and risk associated with repeat manufacturing programs and provides more certainty for PharmAust’s clinical trial scheduling.”

This announcement is authorised by the Board.

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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.