PharmAust establishes monepantel GMP tablet stability

- Ongoing stability data for monepantel show long tablet shelf-life with specifications remaining well within limitations for both veterinary and human use
- Product stability and shelf-life are important as PharmAust moves toward a Phase III trial and identifies potential commercial partners

7 July 2021 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage biotechnology company, is pleased to report that after formally testing monepantel tablets for 24 months in storage at a controlled temperature of 25°C with 60% humidity, the tablets remain within specifications relevant for both veterinary and human clinical trials.

This is after two independent GMP-grade stability studies from two independent GMP manufacturing programs. Tablet stability data result from periods of up to 24 months and 19 months storage from these two independent programs.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "The stability data for the tablets currently being used for veterinary work provides great confidence that the next round of GMP tablets manufactured for human testing will similarly meet required specification levels. Having a robust GMP tablet significantly reduces costs associated with repeat manufacturing programs and provides certainty for PharmAust's clinical trial scheduling."

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 $3.5 million in revenue in FY 2020.

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.