



Phase I Monepantel Tablets Demonstrate High Safety

- Groups of healthy beagle dogs successfully administered either 2, 4, 7 or 10 tablets in Phase I single dose escalation study.
- No adverse clinical signs observed following administration at any dose.
- No apparent taste issues for dogs even after taking 10 tablets.
- Successful administration of 10 tablets provides an excellent safety margin.
- Guiding dosing strategy for upcoming anti-cancer Phase II trial

28 March 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce that it has received further positive results from its ongoing Phase I trial programme in healthy beagle dogs.

This latest trial tested the safety of monepantel tablets in an escalating single dose study. The beagles were sequentially treated with either 2, 4, 7 or 10 tablets and then monitored over three days for the appearance of any adverse clinical signs. Monepantel tablets were very well tolerated at all levels. No adverse effects, toxicity or safety related observations were reported by the US-based independent research organisation conducting the study.

This also follows PharmAust's 14 March announcement that reported that one tablet was sufficient to provide blood levels that associate with anti-cancer activity. The lack of adverse effects following administration of 10 tablets attests to an excellent safety margin for anti-cancer treatment.

Importantly, for the Phase II study due to begin on completion of the imminent 28-day pharmacokinetic (PK) programme, no apparent taste issues were noted for dogs that were administered 10 tablets in one dose. This observation attests to the high palatability and tolerance of the new tablet formulation when compared to the previously used liquid formulation. PharmAust has now administered 61 tablets on 29 occasions to over 20 individual healthy beagle dogs and no adverse effects have been recorded.

With this very high safety margin PharmAust will now commence daily repeat dosing tests to determine how best to maintain long term monepantel blood levels that correlate with enduring anti-cancer activity.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "These results continue to support the very high safety profile associated with monepantel. The results further provide the Company and its clinical associates with insight on a dosing strategy that will optimise the

anti-cancer activity of monepantel in the upcoming Phase II trial. In the future it is envisaged that pet owners will be able to administer these tablets very simply to their dogs at home."

Enquiries:

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About PharmAust (PAA):

PAA is a clinical-stage company developing targeted cancer therapeutics for humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. PAA's subsidiary, Epichem, is a successful contract medicinal chemistry company that generated \$3m revenues in FY2018.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a key driver of cancer. MPL has been evaluated in Phase 1 clinical trials in humans and dogs; was well tolerated and produced a significant reduction in key prognostic biomarkers. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug to Phase 2 clinical trials.

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