Phase IIb Clinical Trial of Monepantel in Pet Dogs with Treatment Naïve B Cell Lymphoma

- Five dogs have completed trial assessment
- Inappetence side-effects appear marginalised by current dose reduction
- Interim determination of MPL and MPLS in blood plasma to be evaluated to correlate target doses with outcomes
- Recruitment for trial continues

30 March 2021 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage oncology company, is pleased to provide an update on its Phase IIb trial evaluating the effects of monepantel upon pet owners' dogs with treatment-naïve B cell lymphoma.

To date, six dogs with stage 4 to 5 B-cell lymphoma have completed assessment across the five participating trial sites. Treatment of one dog was not in compliance with the dosing instructions (MPL after meal) and that dog was withdrawn from the trial.

Some mild and occasional inappetence was reported in some dogs but this appears insignificant and difficult to attribute solely to MPL. Pleasingly, side-effect levels to date are below those of other conventional anticancer drugs and trial veterinarians report that, at day 28, all participating dogs have been in good spirits and well within themselves. As such the owners have elected to continue treating their dogs with MPL on compassionate use, post-trial.

A further six pet dogs that did not meet the trial inclusion criteria are also being treated under compassionate use with MPL in varying combinations with other anticancer drugs.

Importantly, PharmAust will perform an interim analysis of MPL and MPLS blood levels being achieved in this trial. Determination of these levels will provide a conservative baseline threshold for the very satisfactory side-effect profile observed. The levels will also provide invaluable information for establishing future stand-alone and/or combination treatment regimens for Phase III trials in dogs.

Furthermore, the pharmacokinetic data extracted will provide important information for forthcoming trials in humans.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "It is very satisfying to see minimal side effects after the observed inappetence during the first trial with the tablets. This gives PharmAust plenty of room to further monepantel testing as a standalone therapy or in combination with other drugs in future larger trials."

University of Melbourne Senior Lecturer (Oncology) Dr Claire Cannon, the principal investigator overseeing the trial, stated, "Monepantel is being well tolerated by the dogs in this study to date with most dogs having no adverse events reported and those that were reported being mild."

The Phase IIb trial is still recruiting and progressing. The principal investigator is evaluating results and trial data release will occur when clear and meaningful outcomes become apparent.

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.