



Pitney Pharmaceuticals
Pty Limited

Phase IIb Clinical Trial in Pet Dogs with B Cell Lymphoma Identifies Therapeutic Window for Monepantel

- Monepantel blood plasma levels assessed from six dogs in the Phase IIb trial
- Current trial provides an indicative optimal plasma level and target therapeutic dose
- PharmAust will continue recruitment to obtain further supportive evidence for efficacy to support a Phase III registration trial

27 April 2021 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage oncology company, is pleased to announce that interim analysis of its Phase IIb trial has provided further supportive evidence of the monepantel blood plasma levels required to suppress B cell lymphoma growth in pet owners' dogs.

PharmAust is now in a good position to further optimise treatment levels of MPL to facilitate a Phase III study. Monepantel in this stage of the study indicated no material adverse events.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "As per the previous high-dose trial using monepantel tablets, a range of drug blood plasma levels was again observed in this lower dose trial, but this time all within a narrower spread. Examination of the blood plasma data in the context of the previous trial, while referencing side effects and efficacy, has reinforced our understanding of a target therapeutic window for monepantel's use in dogs with B cell lymphoma. The Phase IIb trial will continue to increase recruitment numbers to gain sufficient information for a future Phase III registration trial."

PharmAust's Chairman, Dr Roger Aston stated, "This represents a material advance in optimising the treatment regimen for canine patients with B-Cell lymphoma and may have applicability to other anti-cancer treatments in companion animals and in humans. Cancer therapy is all about optimising efficacy and minimising adverse events and this is particularly important with aggressive late-stage cancers such a Stage 4/5 B-Cell lymphoma. Following a Phase III trial PharmAust will also examine how monepantel can be integrated into the current standard of care."

This announcement is authorised by the Board.

Enquiries:

Dr Roger Aston
Executive Chairman and CEO
Tel: 0402 762 204
rogeraston@pharmaust.com

Dr Richard Mollard
Chief Scientific Officer
Tel: 0418 367 855
rmollard@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 \$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.