First Patient in US Canine Cancer Trials Begins Treatment

7 September 2022 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company has recruited the first pet dog with B cell lymphoma in its US canine Phase 2 trial assessing the efficacy of Monepantel (MPL) treatment.

Dr Meighan Daly DeHart and the medical oncology team at Pathway Vet Alliance dba as Thrive Pet Healthcare and Heart of Texas (HoT) Veterinary Specialty Center in the US will treat up to 10 dogs according to FDA pilot program guidelines.

Within the last week the first dog passed a physical exam and standardised staging tests and was sent home to commence treatment with MPL tablets. The dog will be required to return for appraisal on Days 14 and 28 at Heart of Texas with Dr Daly DeHart.

Principal Investigator, Dr Kim Agnew stated: "It is very exciting to start the first enrolment in the US. During a recent visit to the study site I found the team at Heart of Texas provide very compassionate patient-focused treatment and I know the study enrolments are in exceptional hands. The clinic experiences a high oncological case load so we are hopeful the enrolment rate will be expedited."

Status of current trial

Veterinary trial centres have been set up in Australia, New Zealand and the United States to evaluate the anti-cancer benefit of MPL in dogs newly diagnosed with B-cell lymphoma and have not received any previous cancer treatment.

PharmAust is recruiting pet dogs with untreated B cell lymphoma to finalise the Phase 2 evaluation of the drug MPL, which has demonstrated effective anti-cancer activity and minimal side effects.

Current study status

The table below outlines the status of all dogs in the study. Please note the explanation of the definitions used in the table.

#Dogs fully completed study*	# Dogs partially completed study**	# Dogs fully completed study - suboptimal blood levels***	#Dogs withdrawn from study****	Total # dogs enrolled to date
16	8	5	4	33

*Fully completed -- All study assessments complete, final grading confirmed PLUS blood testing for Monepantel completed. **Monepantel levels are in optimum range**

Partially completed – All study assessments complete, final grading confirmed. Blood testing for Monepantel **NOT completed

*** All study assessments are complete, final grading confirmed PLUS blood testing for Monepantel completed. Monepantel **levels in sub-optimum range**

**** Dogs withdrawn from the study due to lack of compliance with study protocol (usually due to dosing dogs incorrectly or given therapy not allowed in protocol)

Twenty-nine pet dogs have been treated using MPL monotherapy. With continued positive outcomes, PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent Phase 3 registration trial.

Of the 16 pet dogs with optimum blood levels, 13 have achieved stable target lesions. This includes one dog with a partial response (60% regression).

Nine of the 16 dogs with optimum blood levels have achieved stable disease by RECIST (Response Evaluation Criteria in Solid Tumours). Side effects were minimal or not detected.

PharmAust requires greater than or equal to 18 dogs with a clinical benefit out of 46 dogs to meet its statistical endpoint.

MPL is already approved for veterinary use for a different indication in food-chain animals. PharmAust is endeavouring to repurpose MPL as a safe and effective cancer treatment without the associated side effects of chemotherapy.

For further information on the study and to read the experiences of other enrolled pets and their parents visit https://www.pharmaust.com/veterinary-trial-testimonials/

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.