PharmAust receives ethics approval to begin Phase II Dog Cancer Trial

- Ethics approval to use new GMP monepantel tablets to treat dogs with cancer
- Testing short-term anti-cancer efficacy and long-term anti-cancer maintenance
- Scaled GMP monepantel tablet manufacture remains on track for imminent delivery
- Phase II trial on track to commence in August/September

15 July 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce receipt of ethics approval from the NSW Department of Primary Industry's Secretary's Animal Care & Ethics Committee to recommence Phase II clinical trials in pet owners' dogs with cancer using its newly formulated tablet.

PharmAust previously received ethics approval for its anti-cancer program in dogs using the currently approved liquid formulation of monepantel. However, despite demonstrating strong signs of anti-cancer efficacy this formulation was unpalatable and could not be used effectively. PharmAust therefore developed a new taste-neutral tablet now approved for Phase II.

Authorities consider the newly developed monepantel tablet a new veterinary research product. As such rigorous tests to demonstrate compliance with regulatory and ethical standards have been conducted by PharmAust in recent months and include the successful tablet safety and blood level tests as announced on 6 May.

Following review of its application, the independent Ethics Committee approved the investigation of monepantel tablets for: (i) testing anti-cancer efficacy in short-term studies and (ii) testing anti-cancer maintenance in long-term studies. Anti-cancer efficacy is measured by achieving stable disease and progression-free survival or regression of the tumour(s). Preventing spread (metastasis) of the cancer will also be monitored.

PharmAust can also report that the scaled manufacture of the new GMP quality tablet is completed. The tablet shelf-life stability tests will be finalised mid-August and these are required before the tablet can be distributed to veterinarians for administration to dogs with cancer. Previous batches of the new tablets have passed stability testing so it is expected that this new batch will comply and then be ready to use.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "PharmAust anticipates delivery of the tablets from the USA in August/September and then recruitment can commence for the Phase II trials shortly thereafter. PharmAust aims to first treat dogs with B-cell lymphoma, the most prevalent canine cancer. PharmAust is looking forward to helping these dogs with cancer admitted to the trials"

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):
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 AUD3.0m in revenues in the 2018 FY.