Phase II Dog Lymphoma Trial Confirms Monepantel Clinical Benefit

- ***Pilot clinical study achieved primary endpoints for safety and efficacy***
- ***6 out of 7 dogs achieved stable disease and reduction in tumour size***
- ***Monepantel: first mTOR inhibitor shown to reduce cancer in dogs***
- ***Outcome supports progression to clinical trial using reformulated monepantel***

13 December 2017 – Perth, Australia: PharmAust Limited (ASX: PAA), a clinical stage oncology company, is pleased to announce that its Phase II dog lymphoma pilot study has successfully concluded achieving its key primary endpoints of safety and efficacy. Six of seven dogs diagnosed with B-cell lymphoma and treated with monepantel (MPL) developed stable disease (86%), one dog developed progressive disease (14%) and there was a median reduction in tumour size of 4%.

The objective of the trial was to assess the efficacy of its lead molecule, MPL, as a first line therapy in dogs diagnosed with B-cell lymphoma that had not received any previous chemotherapy. The dogs were treated for two weeks with daily doses of MPL as first-line therapy before commencing conventional chemotherapy. The primary endpoints were safety and clinical efficacy.

B-cell lymphoma was chosen as the target indication as it's the most commonly treated cancer in dogs.

Principal Investigator Dr Angela Frimberger said, "We were pleased to observe that after two weeks of daily treatment with MPL alone, six out of seven dogs achieved stabilisation of their cancers, reductions in tumour sizes and no significant side-effects. This is an extremely progressive cancer; without effective treatment dogs diagnosed with lymphoma would typically show progressive disease after two weeks. So, stabilisation of disease is a positive clinical benefit according to standard criteria for measuring tumour responses."

"Furthermore, given the excellent safety margin we are seeing we expect the optimum clinical dose of the drug, once reformulated, will be substantially higher than the dose we have been using. To me, this means that monepantel has definite potential to benefit dogs with cancer and we should continue into a full clinical trial."

PharmAust CEO, Dr Richard Hopkins, commented "We are really pleased with the outcome to this pilot study which, according to our advisory team, strongly supports further clinical evaluation of monepantel. Monepantel will be the first mTOR inhibitor tested as a cancer therapy in dogs and has potential to address a major unmet need for new drugs in the pet cancer market."

PharmAust is expecting to launch its clinical trial program using reformulated MPL in early 2018.

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About PharmAust (PAA):
PAA is a clinical-stage company developing targeted cancer therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are support by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company which is forecast to generate ~Aus$4m in revenues in the 2018 FY

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. MPL treatment 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 into Phase 2 clinical trial.