Phase II dog lymphoma trial preliminary results demonstrate Monepantel clinical benefit

- ***3 out of 4 dogs achieved stable disease and tumour size reduction***
- ***First evidence Monepantel is active against tumours in dogs***
- ***Study ongoing with results from 10 dogs slated for Q3 2017***

19 May 2017 – Perth, Australia: PharmAust Limited (ASX: PAA) has received preliminary analysis from its Phase II dog lymphoma trial that showed three out of four dogs treated with Monepantel (MPL) achieved stable disease and reduction in tumour size. This is the first evidence that MPL is directly active against tumours in dogs, and is consistent with outcomes observed in a recent Phase I human trial.

The primary objective of the current trial is to assess the efficacy of MPL as a first line therapy in dogs diagnosed with lymphoma that have not received any previous chemotherapy. The study allows dogs to be treated for two weeks with daily doses of MPL as first-line therapy before commencing conventional chemotherapy. The primary endpoints are safety and clinical efficacy.

Lymphoma was chosen as the target indication as it represents the most commonly treated cancer in dogs and is known to be responsive to drugs targeting the mTOR pathway in humans.

Principal Investigator Dr Angela Frimberger said, "This study builds on ongoing Phase I/II clinical trials in dogs using MPL, showing that the drug is well tolerated and biologically active in terms of its ability to reduce expression of clinically-relevant biomarkers. However, the dogs treated in earlier studies had late-stage cancers that had already failed standard of care treatments, which made it a challenge to try and interpret the clinical benefits from those earlier trials.

"To address this, the current trial uses MPL as first-line therapy in dogs diagnosed with lymphoma. We were encouraged to observe that after two weeks of daily treatment with MPL only, three out of four dogs achieved stabilisation of their cancers along with reductions in tumour sizes. Measurements ranged from 2-19% reduction in tumour volume with an average of 11% being achieved across all three dogs. Without effective treatment, dogs diagnosed with lymphoma would typically show progressive disease after two weeks.

"It is true that the levels of tumour reduction after this short treatment window met the definition of Stable Disease, rather than Partial Response, which requires >30% reduction in tumour size. However because lymphoma is so rapidly progressive without effective treatment, this preliminary outcome indicates the drug is showing clinical activity against the tumours.

"Importantly, given the excellent safety margin we are seeing, we expect the optimum clinical dose of the drug will be significantly higher than the dose we have been using. The fact we are seeing some clinical anti-cancer effect at the present dose is particularly encouraging," added Dr Frimberger.

The study is ongoing at multiple sites including the Animal Referral Hospital in Homebush, NSW and Queensland Veterinary Specialists in Brisbane, QLD. The study is aiming to recruit up to 10 dogs with final results expected approximately Q3 2017.

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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 synthetic drug manufacturer which is forecast to generate Aus$3m in revenues in 2017 at a CAGR of 28%.

PAA's lead drug candidate is Monopantel (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. Further, 50% of end-stage Individuals achieved stable disease at low therapeutic doses providing support for MPL efficacy observed in preclinical studies.

PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug into Phase 2 clinical trial.

About NewSouth Innovations (NSi): NSI are a commercialisation company responsible for the protection and management of Intellectual Property (IP) developed at the University of New South Wales (UNSW). PharmAust acknowledges that the IP referred to in this announcement was assigned to Pitney Pharmaceuticals, a subsidiary of PharmAust, from the University of New South Wales in 2013