



PharmAust Signs Agreement for US Phase I Trials in Dogs

- Monepantel tablets to be tested in Phase I healthy dog trial due to commence 19th February 2019
- Designed to provide information on tablet number, administration frequency, blood levels and verification of safety for the Phase II trials in pet owners' dogs with naturally occurring cancers
- Successful Phase I trial design in dogs also to be used as a bridging study to support US FDA IND application for clinical trials in humans.

7th February 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, has executed an agreement with a major US Contract Research Organisation, to commence Phase I clinical trials with the newly formulated monepantel tablet.

The Phase I trial design has four stages:

- (i) validating the optimal dietary conditions for monepantel administration – e.g. to take on a full or empty stomach,
- (ii) confirming the safety of monepantel at single dose in a dose escalation study,
- (iii) determining the frequency of dosing required (every second or third day, for example) to achieve blood levels predicted to be compatible with anticancer activity, and
- (iv) based upon (i), (ii) and (iii), establish a 28 day repeat-dose drug level study to determine optimal tablet administration frequency as a prelude to commence the Phase II anticancer studies in pet owners' dogs with cancer.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "PharmAust is very pleased to enter into this agreement. The trial design should provide the required information to enable the best possible treatment for pet owners' dogs with cancer in the upcoming Phase II trials. Further, because monepantel is now in a tablet instead of a liquid, the safety component of this trial design would potentially form part of the bridging component required for regulatory authorities such as the FDA for establishing an Investigative New Drug Application for clinical trials in humans".

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 ~Aus\$3.02m in revenues in the 2018 FY.